

EXHIBIT D

Steven MacLean, Ph.D., P.E.

Page 1

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC : Master File No.
REPAIR SYSTEM PRODUCTS : 2:12-MD-02327
LIABILITY LITIGATION : MDL NO. 2327
: :
: JOSEPH R. GOODWIN
: U.S. DISTRICT JUDGE
THIS DOCUMENT RELATES TO : :
PLAINTIFFS: : :
: :
Ida Evans : :
2:12-cv-01225 : :
: :
Rose Gomez : :
2:21-cv-00344 : :
: :
Jeanie Holmes : :
2:12-cv-01206 : :
: :
Mary Jane Olson : :
2:12-cv-00470 : :
: :
Christine Wiltgen : :
2:12-cv-01216 : :
: :
Kathleen Wolfe : :
2:12-cv-00337 : :
: :
Monica Freitas : :
2:12-cv-01146 : APRIL 18, 2016
: :
Denise Sacchetti : :
2:12-cv-01148 : :
: :
Sheri Scholl : :
2:12-cv-00738 : :
: :
Cindy Smith : :
2:12-cv-01149 : :
: :
Waynick, Laura : :
2:12-cv-01151 : :

DEPOSITION OF STEVEN MACLEAN, Ph.D., P.E.

Steven MacLean, Ph.D., P.E.

	Page 2		Page 4
1 Caption Continued:		1 Deposition of STEVEN MACLEAN, Ph.D., P.E.,	
2 Denise Burkhardt :		2 taken before and by Janis L. Ferguson, Notary	
3 2:12-cv-01023 :		3 Public in and for the State of New York, on	
4 Jo'Ann Lehman :		4 Monday, April 18, 2016, commencing at 8:41 a.m.,	
5 2:12-cv-00517 :		5 at the Rochester Airport Marriott, 1890 Ridge	
6 Patricia Ruiz :		6 Road West, Rochester, New York 14614.	
7 2:12-cv-01021 :		7	
8 Pamela Free :		8	
9 2:12-cv-00423 :		9 A P P E A R A N C E S	
10 : :		10	
11 : :		11 For the Plaintiffs:	
12 : :		12 Daniel Thornburgh, Esquire	
13 : :		13 Aylstock Witkin Kreis and Overholtz, PLC	
14 : :		14 17 E. Main Street, Suite 200	
15 : :		15 Pensacola, FL 32502	
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18 : :		18 For the Plaintiff Pamela Free: (Via teleconference)	
19 : :		19 Joseph Kramer, Esquire	
20 : :		20 Tor Hoerman Law LLC	
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24 : :		24 joe@thlawyer.com	
	Page 3		Page 5
1 Caption Continued:		1 I N D E X	
2 Karyn Drake :		2	
3 2:12-cv-00747 :		3 TESTIMONY OF STEVEN MACLEAN, Ph.D	
4 Paula Kriz :		4 EXAMINATION BY: PAGE	
5 2:12-cv-00938 :		5 Attorney Thornburgh 7	
6 Stacy Shultis :		6 Attorney Thomas 129	
7 2:12-cv-00654 :		7 Attorney Thornburgh 132	
8 Kimberly Thomas (Wyatt) :		8	
9 2:12-cv-00499 :		9	
10 Myndal Johnson :		10 MACLEAN DEPOSITION EXHIBIT PAGE	
11 2:12-cv-00498 :		11 No. 1 - Notice of Deposition 13	
12 Beverly Kivel :		12 No. 2 - Thumb Drive 15	
13 2:12-cv-00591 :		13 No. 3 - MacLean Expert Report 15	
14 Karen Bollinger :		14 No. 4 - MacLean Supplemental Report Wave 1 16	
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17 2:12-cv-01081 :		17 No. 7 - Binder of Published Literature 18	
18 Shirley Walker :		18 No. 8 - Clavé Article 19	
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20 Dawna Hankins :		20 No. 10 - Plaintiffs Experts' Reports 24	
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1	STEVEN MACLEAN, Ph.D., P.E., first	
2	having been duly sworn, testified as follows:	
3		
4	EXAMINATION	
5	BY MR. THORNBURGH:	
6		
7	Q. Good morning, Dr. MacLean.	
8	A. Good morning.	
9	Q. How are you?	
10	A. I'm well. How are you?	
11	Q. Good. My name is Daniel Thornburgh. And you	
12	and I have met before in a prior deposition?	
13	A. We have.	
14	Q. And you understand that you're here to give	
15	deposition testimony in the Wave 1 cases?	
16	A. Correct.	
17	Q. Okay. And you've given deposition testimony	
18	before, and so you know the ground rules. I'm not	
19	going to go through all of them.	
20	But I would ask that if you don't understand	
21	a question that I ask, let me know. Okay?	
22	A. (Witness nods head.)	
23	Q. If you answer the question, I'm going to	
24	assume that you understood it, and then we'll just move	

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<p>1 Q. And did you offer testimony in your capacity 2 as an employee for Exponent? 3 A. I offered expert testimony as an expert in 4 polymer science. 5 Q. As an employee of Exponent. 6 A. As an employee of Exponent, correct. 7 (Discussion held off the record.) 8 Q. Doctor, before we mark this exhibit, you 9 haven't personally analyzed any explanted polypropylene 10 meshes, correct? 11 A. I have. 12 Q. Okay. Since -- did you do that in this case? 13 A. I did that in the last few months, over the 14 last few months. 15 Q. Okay. 16 A. It was with regard to certain explants from 17 Wave 1. 18 Q. Which Wave 1 explants did you analyze? 19 A. (No response.) 20 Q. Did you do a case-specific report? 21 A. I did -- for those particular explants? 22 Q. Right. 23 A. I did not. 24 Q. Okay.</p>	<p>1 A. Just examined it under the microscope after 2 the case was either settled or dismissed. I can't 3 recall the outcome of that case. 4 Q. There was some leftover material from that 5 lawsuit that you analyzed? 6 A. Correct. 7 Q. And what was the purpose of analyzing the 8 blue material? 9 A. Just to look at the mesh with the tissue 10 around it. 11 Q. Because you had not done it previously? 12 A. Not prior to that. 13 Q. So you were just trying to get sort of an 14 idea of what it looked like? 15 A. I would say to just have an opportunity to 16 see it first-hand. 17 Q. What did you do? Just look at it by optimum 18 microscopy? 19 A. Looked at it optically. Also looked at it 20 under scanning electron microscopy. 21 Q. Okay. And you didn't perform any FTIR or any 22 other analysis? 23 A. I don't believe so. On that particular mesh. 24 Q. We'll get back to the Plaintiffs that you've</p>
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<p>1 A. The first one is Kathy Barton, B-A-R-T-O-N. 2 The second one is Michelle Bellito-Stanford. 3 B-E-L-L-I-T-O. The third one is Barbara Bridges, 4 B-R-I-D-G-E-S. Mary Jean Simpson. Margaret 5 Stubblefield, S-T-U-B-B-L-E-F-I-E-L-D. Charlene 6 Taylor, T-A-Y-L-O-R. And last one is Mary 7 Wise-Turner, W-I-S-E - T-U-R-N-E-R. 8 Q. Are these the first set of explanted mesh 9 material that you've analyzed as a polymer scientist? 10 A. Analyzed, no, because I've analyzed scores of 11 data from other explants. 12 Q. Data that was reported by other -- other 13 witnesses, other experts? 14 A. By other researchers, experts, Ethicon 15 themselves, correct. 16 Q. But this is the first time -- this batch of 17 Plaintiffs, this is the first time that you've 18 personally conducted or oversaw the analysis of 19 explanted mesh material. 20 MR. THOMAS: Object to form of the question. 21 A. This will be at least the second time, 22 because I did some work with the blue explant a few 23 years ago. A year or so ago. 24 Q. What work did you do with the blue explant?</p>	<p>1 looked at their mesh specimens later on today. Okay? 2 A. Okay, sure. 3 (MacLean Deposition Exhibit 1 - Notice of 4 Deposition - marked for identification.) 5 Q. Doctor, I've marked as Exhibit No. 1 the 6 Notice of Deposition. Have you seen this document 7 before? 8 A. I have. 9 Q. And attached to the Notice and the Schedule A 10 that asks for a set of document requests, have you gone 11 through this Schedule A to look for any documents that 12 were responsive to this request? 13 A. I have. 14 MR. THOMAS: Dan, just so you know, you know 15 we filed a response to the Notice? 16 MR. THORNBURGH: Okay. 17 MR. THOMAS: Okay? 18 Q. Were there any documents that you felt were 19 responsive to the request that you did -- that you did 20 not produce? 21 MR. THOMAS: Objection. There are a number 22 of the documents that we've objected to 23 producing in the response to the -- to the Notice. If you want to go through those one</p>

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<p style="text-align: right;">Page 14</p> <p>1 by one, I'm happy to, but I think you'll find 2 that his complete file that he relies on for 3 his opinions in the case has been produced. 4 Q. Let me ask you this question: Did you 5 conduct any testing or analysis of -- in this 6 litigation that you did not produce the underlying data 7 for?</p> <p>8 A. No.</p> <p>9 Q. So you've produced all of the underlying data 10 related to all of the testing that you conducted in 11 this case.</p> <p>12 A. For Wave 1, yes, correct.</p> <p>13 Q. For Wave 1. And that was produced to me 14 electronically yesterday. I wasn't able to print out 15 any -- hardly any documents from that. Did you bring 16 any documents with you today? I see some notebooks. 17 A. I did.</p> <p>18 Q. Let's go ahead and mark those documents. 19 A. Okay.</p> <p>20 MR. THOMAS: For your information, Dan, he's 21 got a thumb drive in his computer which is 22 the complete set of what was sent to you 23 yesterday. If you want to mark the thumb 24 drive as well.</p>	<p style="text-align: right;">Page 16</p> <p>1 B-E-C-K-E. 2 Q. And what does "Becke" mean? 3 A. It's -- refers to a Becke line, which can be 4 an artifact of optical microscopy. 5 Q. Okay. We'll talk about that in a little bit. 6 Do you have any -- other than what's contained with 7 your report, did you bring any hard copies of the 8 microphotographs? 9 A. Very few. I have them all on the thumb 10 drive, so if there's one particular one you want to 11 focus in on, we can certainly pull it up. 12 Q. Okay. Does Appendix G of Exhibit 3 contain 13 all of the microphotographs that you took in this case? 14 A. It does. 15 Q. Did you take additional microphotographs in 16 your supplemental report of the work that you conducted 17 in the -- to produce the supplemental report? 18 A. Yes. 19 Q. Let's go ahead and mark Exhibit No. 4. 20 (MacLean Deposition Exhibit 4 - Wave 1 21 Supplemental Report of Dr. Steven MacLean - 22 marked for identification.) 23 Q. That is your supplemental report. I'll thumb 24 through it really quick.</p>
<p style="text-align: right;">Page 15</p> <p>1 MR. THORNBURGH: Yeah. We'll go ahead and 2 mark the thumb drive as well. Let's mark the 3 thumb drive as Exhibit No. 2. 4 MR. THOMAS: I'll put the sticker on it. 5 (MacLean Deposition Exhibit 2 - Thumb Drive - 6 marked for identification.) 7 BY MR. THORNBURGH: 8 Q. Okay, I'm going to mark as Exhibit No. 3 a 9 binder that you brought with you today that appears to 10 be your expert report. 11 A. Correct. 12 (MacLean Deposition Exhibit 3 - Expert Report 13 of Dr. Steven MacLean - marked for 14 identification.) 15 Q. I'm going to thumb through it real quickly. 16 A. By all means. 17 Q. And there's some highlighting on this report. 18 Are these highlighting -- is this highlighting that you 19 made? 20 A. My highlighting, correct. 21 Q. On Exhibit 3, there's a tab. Can you tell me 22 what that tab says. It's on Page 68 of your expert 23 report. I just can't read your handwriting. 24 A. Yep. No, that's fine. It's Becke,</p>	<p style="text-align: right;">Page 17</p> <p>1 Okay. And Exhibit No. 4, there are a number 2 of separated -- looks like two microphotographs or 3 copies of microphotographs of -- it looks like the 4 chemical-treated specimens. 5 A. Correct. 6 Q. I'm going to go ahead and mark those 7 separately as Exhibit No. 5. 8 (MacLean Deposition Exhibit 5 - 9 Microphotograph - marked for 10 identification.) 11 Q. And Exhibit No. 6. 12 (MacLean Deposition Exhibit 6 - 13 Microphotograph - marked for 14 identification.) 15 Q. I don't see an appendix on exhibit to your 16 supplemental report that contains the images that we 17 saw in your original report, which was the 18 microphotographs. Is it fair to say that you did not 19 attach the microphotographs to your -- strike that. 20 Is it fair to say that you did not attach to 21 your supplemental report, or at least what you brought 22 with you today, the microphotographs of the work that 23 relates to the supplemental report? 24 A. I did not print hard copies of those,</p>

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<p>Page 18</p> <p>1 correct. But, again, they're on the hard drive. 2 Q. Right. I'll hand you back Exhibit No. 3 and 3 4. 4 (Discussion held off the record.) 5 Q. We'll just keep those out so the court 6 reporter can find them as well. 7 A. Sure. 8 (MacLean Deposition Exhibit 7 - Binder of 9 Published Literature of Dr. Steven MacLean - 10 marked for identification.) 11 Q. Okay. We've marked as Exhibit No. 7 a binder 12 that you brought with you today that appears to be some 13 published literature? 14 A. (Witness nods head.) 15 Q. Is that correct? 16 A. It is correct. 17 Q. There are a couple of additional documents in 18 the sleeve of Exhibit No. 7 that I'll mark as separate 19 exhibits. The highlighting that's contained within -- 20 or on any of these publications, who highlighted 21 those? 22 A. I did. 23 Q. And are the electronic copies of those 24 publications also contained on your thumb drive?</p>	<p>Page 20</p> <p>1 Q. Was the first time that you looked at the -- 2 did you first read the articles that are summarized in 3 Exhibit No. 9 in conjunction with the work that you did 4 in your -- in drafting your supplemental report? 5 A. Could you just repeat that. 6 Q. Yeah. 7 MR. THORNBURGH: Can you read that back. 8 (Record read back by the reporter.) 9 A. No. Many of those pieces of literature I 10 read over a year ago. 11 Q. Okay. So this was just a re-review of the 12 articles -- 13 A. Correct. 14 Q. -- and publications? 15 A. Correct. Just to try to keep it all 16 straight. 17 Q. When we met in the Mullins litigation and I 18 took your deposition, you had issued a report in that 19 case; the consolidated TTVT set of cases. And you had 20 testified during your deposition that you had help from 21 your technicians or staff members at Exponent in 22 drafting your expert report in the Mullins case. 23 A. I had some assistance with some of the 24 sections of the report, correct. Initial drafts of the</p>
<p>Page 19</p> <p>1 A. They are. 2 Q. I'll mark as Exhibit No. 8 the Clavé article, 3 which was in the sleeve of Exhibit No. 7. 4 (MacLean Deposition Exhibit 8 - Clavé Article 5 - marked for identification.) 6 Q. And looks like a summary of some of the 7 publications. Correct? 8 A. Correct. 9 Q. Which I'll mark as Exhibit No. 9. 10 (MacLean Deposition Exhibit 9 - Summary of 11 Publications - marked for identification.) 12 Q. Who drafted the summaries of these 13 publications? 14 A. I did. 15 Q. When did you draft this? 16 A. Several weeks ago. 17 Q. Was that in conjunction with the work that 18 you did on the supplemental report? 19 A. I would say it was during the same time as 20 the supplemental report was being drafted. 21 Q. Did you make any notes of any of the 22 publications prior to submitting your Wave 1 report? 23 A. Those would be the only notes I have on the 24 literature that I've taken. I don't recall the timing.</p>	<p>Page 21</p> <p>1 report. 2 Q. Okay. Did you have any assistance in -- from 3 your staff or technicians in drafting your first 4 expert report, your primary expert report that was 5 issued in the Wave 1 cases? 6 A. I did, but it was fairly limited, because 7 the -- it was only some additional sections from the 8 Mullins report that were added into the supplemental. 9 Q. I'm talking about -- 10 A. I'm sorry. 11 Q. -- the initial report, yes. 12 A. Yes. 13 Q. And then what about your supplemental report? 14 Did you have assistance in drafting that report from 15 staff members or employees of Exponent? 16 A. I did. I had two colleagues that assisted 17 with that work. 18 Q. And what are their names? 19 A. Dr. Garcia and Dr. Benight. 20 (Witness asked for clarification by the 21 reporter.) 22 A. B-E-N-I-G-H-T. 23 Q. And who helped you with drafting the -- some 24 of the sections in your Wave 1 primary initial report?</p>

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<p style="text-align: right;">Page 22</p> <p>1 A. Dr. Moll. 2 Q. Okay. 3 A. And Dr. McGann. M-O-L-L, M-C-G-A-N-N. 4 Q. For your first report in Wave 1 -- we'll 5 call it your primary report -- what sections were 6 drafted by the employees of Exponent? 7 A. I think we'd have to go look at the report 8 and look at the additional sections. 9 (Discussion held off the record.) 10 A. So Dr. Moll and I had worked on the Mays 11 section, M-A-Y-S. Dr. McGann and I worked on the 12 Priddy section, P-R-I-D-D-Y. And Dr. Moll and I worked 13 on the Klinge, K-L-I-N-G-E, section. 14 Q. And are those -- those sections represent the 15 only additions to your report that was issued in the 16 Mullins case? 17 A. Not exactly. So in this -- in the Wave 1 18 report, I consolidated the original microscopy report 19 with the Mullins report, so that, arguably, is also an 20 addition. 21 Q. Right. 22 A. And I think that is the total of the 23 additions, compared from -- Mullins, compared to Wave 24 1.</p>	<p style="text-align: right;">Page 24</p> <p>1 A. They're not technicians. They're -- they are 2 Ph.D. scientists. And I don't recall which sections 3 exactly. We went through that report several times. I 4 couldn't parse out which sections they helped with and 5 which ones they didn't. 6 Q. Okay. Well, we'll go through it -- 7 A. Okay. 8 Q. -- in greater detail. 9 A. Sure. 10 Q. I'm going to hand you back Exhibit No. 7, 11 which is the published literature. 12 A. Okay. 13 Q. Here is Exhibit No. 8, which is your 14 marked-up copy of the Clavé study. 15 A. Thank you. 16 Q. And Exhibit No. 9, which is your summary of 17 some of the publications. 18 I'll mark as Exhibit No. 10 a binder that you 19 brought with you that appears to be copies of certain 20 expert reports from the Plaintiffs. 21 (MacLean Deposition Exhibit 10 - Plaintiffs 22 Experts' Reports - marked for 23 identification.) 24 A. Correct.</p>
<p style="text-align: right;">Page 23</p> <p>1 Q. Okay. And regarding your supplemental 2 report, which I think was marked as Exhibit No. 3 -- 2 3 or 3 -- 4 MR. THOMAS: 4. 5 Q. I'm sorry, 4. Who, again, helped you with 6 that report? 7 A. I'm sorry. Which report? 8 Q. You said Dr. Benight and another doctor. 9 A. And Dr. Garcia. 10 Q. Dr. Benight and Dr. Garcia helped you draft 11 the additional sections that were added to the 12 supplemental report? 13 A. I just want to make sure we have all the 14 reports -- 15 Q. Exhibit No. 4. 16 A. So just ask me that one more time. 17 Q. Yeah. Dr. Benight and Dr. -- 18 A. Garcia. 19 Q. -- Garcia, they helped you draft certain 20 sections of the supplemental report. Right? 21 A. Correct. That's correct. 22 Q. Which has been marked as Exhibit No. 4. 23 Which section did those doctors or those technicians 24 assist you with?</p>	<p style="text-align: right;">Page 25</p> <p>1 Q. In the sleeve, there appears to be a 2 deposition excerpt from Dr. Priddy. 3 A. Correct. 4 Q. I'll mark that as a separate exhibit, No. 11. 5 (MacLean Deposition Exhibit 11 - Excerpt of 6 the testimony of Duane Priddy, Ph.D. - 7 marked for identification.) 8 Q. It's two pages. It's 139 and 140 of Dr. 9 Priddy's deposition. 10 A. Correct. 11 Q. And this is an excerpt -- was this excerpt 12 provided to you by Ethicon's counsel? 13 A. No. The entire deposition was provided to me 14 from Ethicon's counsel. That was an excerpt that I 15 took out and highlighted. 16 Q. Okay. And so you did the highlighting of 17 this -- on this document? 18 A. Correct. I read his entire deposition, and I 19 highlighted those sections and pulled them out. 20 Q. Okay. And there's some flags on Exhibit 21 No. 10. Are those flags done by you? 22 A. They were done by me. 23 Q. It looks like all of these flags relate to 24 the expert report of Dr. Iakovlev.</p>

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<p style="text-align: right;">Page 26</p> <p>1 A. It would appear. Just show me the yellow 2 one. You are correct.</p> <p>3 Q. Okay. Are there any documents or materials 4 that you brought with you today that we have not 5 marked?</p> <p>6 A. No. I believe that's everything.</p> <p>7 Q. Dr. MacLean, when were you retained by 8 Ethicon as an expert in the Wave 1 cases? Actually, 9 this might help you out.</p> <p>10 (MacLean Deposition Exhibit 12 - June 15, 11 2015 letter from Steven MacLean to Chad R. 12 Hutchinson - marked for identification.)</p> <p>13 Q. I've marked as Exhibit No. 12 a letter -- 14 looks like it's from Exponent to Chad Hutchinson, which 15 is a lawyer for Butler Snow, representing Ethicon. It 16 looks like a retention letter.</p> <p>17 A. That is correct.</p> <p>18 Q. Okay. So based on -- according to the 19 retention letter, you were retained formally by 20 letter -- or you accepted the request to be retained on 21 June 15th, 2015. Is that correct?</p> <p>22 A. Correct. That's when this formal letter was 23 written.</p> <p>24 MR. THOMAS: And just to be fair, it's</p>	<p style="text-align: right;">Page 28</p> <p>1 Q. Which Composite Exhibit 13 contains an 2 invoice from July 17th, 2015, in the amount of \$72,174. 3 So about a month after your -- the retention letter, 4 you invoiced Ethicon in this amount. Correct?</p> <p>5 A. Correct.</p> <p>6 Q. So the \$72,174, does that represent payment 7 for the work that was conducted by you or by Exponent 8 related to the retention letter of June 15th, 2015? Is 9 that all work -- strike that.</p> <p>10 Does that invoice represent work that was 11 conducted by you or Exponent after the June 15th, 2015 12 retention letter?</p> <p>13 A. For my projects, correct.</p> <p>14 Q. Okay. So in less than a month, you and/or 15 Exponent billed Ethicon for \$72,174.</p> <p>16 A. We provided services that equated to \$72,174.</p> <p>17 Q. Okay. What services did you provide from 18 June 15th, 2015 to July 17th, 2015 which represent the 19 billing of \$72,174?</p> <p>20 A. Consulting services.</p> <p>21 Q. What type of consulting services?</p> <p>22 A. We were working on -- at this time we would 23 have been working on the Mullins consolidated cases.</p> <p>24 So I would -- without having any more detail, this work</p>
<p style="text-align: right;">Page 27</p> <p>1 general consulting. I don't think Wave 1 2 existed at the time this letter was written.</p> <p>3 MR. THORNBURGH: Okay.</p> <p>4 Q. So this was general consulting for future 5 work -- future unknown work to be conducted on behalf 6 of -- or as an expert employed at Exponent, 7 representing Ethicon.</p> <p>8 A. It's a retention for mesh-related matters, 9 correct.</p> <p>10 Q. What's your hourly fee, again?</p> <p>11 A. In 2016, it's 380.</p> <p>12 Q. 380. So at the time -- (Discussion held off the record.)</p> <p>13 Q. At the time that you were retained as a 14 general expert in June of 2015, your hourly rate was -- 15 appears to be \$355 per hour?</p> <p>16 A. In 2015, correct.</p> <p>17 Q. Okay. And it has gone up in 2016 to \$380 per 18 hour?</p> <p>19 A. It is now \$380 an hour, correct.</p> <p>20 Q. All right. You also produced a number of 21 invoices. We'll mark it as Composite Exhibit No. 13. 22 (MacLean Deposition Exhibit 13 - Invoices - 23 marked for identification.)</p>	<p style="text-align: right;">Page 29</p> <p>1 would have been in support of that effort, primarily.</p> <p>2 Q. When did you begin your work for the Wave 1 3 cases?</p> <p>4 MR. THOMAS: Object to form of the question.</p> <p>5 A. I don't recall a specific date.</p> <p>6 Q. If you look at the next invoice, it's dated 7 August 13th -- let's see here. August 13th, 2015. And 8 the August 13th, 2015 invoice, which is about a month 9 later from the last invoice that we looked at, is in 10 the amount of \$19,848. Correct?</p> <p>11 A. Correct.</p> <p>12 Q. Was this -- did this -- the work that you 13 conducted and billed for this August 13th invoice, does 14 that relate to the work that you did in the Wave 1 15 litigation?</p> <p>16 A. For the -- I'm sorry; for which invoice? The 17 August 13th invoice?</p> <p>18 Q. August 13th.</p> <p>19 A. No. This would not have included Wave 1.</p> <p>20 Q. The next invoice is dated October 30th, 2015. 21 I'll hand you a copy of that. And this invoice, it 22 doesn't have a total. Doesn't appear to be totaled. 23 Right?</p> <p>24 A. It does not appear to be totaled, unless the</p>

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<p style="text-align: right;">Page 30</p> <p>1 second page is perhaps missing.</p> <p>2 Q. And it looks like it's somewhere north of a</p> <p>3 hundred thousand dollars. Right? I didn't do the</p> <p>4 math, but somewhere north of a hundred thousand?</p> <p>5 A. It's probably somewhere between 90 and a</p> <p>6 hundred thousand dollars.</p> <p>7 Q. Okay. And does the work that's reflected on</p> <p>8 the invoice of October 30th, 2015, which is just two</p> <p>9 months later from the last invoice, does that represent</p> <p>10 any work that was conducted by you or Exponent as it</p> <p>11 relates to the Wave 1 litigation?</p> <p>12 A. My best recollection is no, that this is</p> <p>13 still prior to Wave 1.</p> <p>14 Q. Okay. December 29th, 2015 is the next</p> <p>15 invoice that was produced. And this is an invoice in</p> <p>16 the amount of \$34,781.70. Approximately two months</p> <p>17 since the last invoice. Does any of the work contained</p> <p>18 on the December 29th, 2015 invoice relate to the work</p> <p>19 that was conducted by you in Wave 1?</p> <p>20 A. I don't believe so.</p> <p>21 Q. Here's the January 21st, 2016 invoice. It</p> <p>22 looks like this is in the amount of \$6,078. Is that --</p> <p>23 does this invoice represent any work that was conducted</p> <p>24 by you in Wave 1?</p>	<p style="text-align: right;">Page 32</p> <p>1 A. Roughly between 90 and a hundred thousand.</p> <p>2 Q. And I've got another invoice that is out of</p> <p>3 order. This is from November 24th, 2015, so before the</p> <p>4 work that you conducted on Wave 1. I have marked</p> <p>5 that -- or it's already marked, but I'll hand it over</p> <p>6 to you.</p> <p>7 And this invoice is also not totaled, but it</p> <p>8 looks -- appears to be somewhere around \$80,000,</p> <p>9 approximately. A little more than that.</p> <p>10 A. Somewhere in that ballpark, correct.</p> <p>11 Q. Okay. So the -- and you've -- going back to</p> <p>12 the last invoice, March 15th, 2016, you have and</p> <p>13 Exponent has conducted additional -- or has performed</p> <p>14 additional services or work for Exponent [sic] since</p> <p>15 March 15th, 2016, correct?</p> <p>16 MR. THOMAS: Object to form. I think you --</p> <p>17 A. Yeah.</p> <p>18 MR. THOMAS: -- said we did the work for</p> <p>19 Exponent.</p> <p>20 Q. I'm sorry. Let me re-ask the question.</p> <p>21 Since the March 15th, 2016 invoice, Exponent</p> <p>22 or yourself has performed additional services on behalf</p> <p>23 of Ethicon, correct?</p> <p>24 A. Are you asking me since March 15th?</p>
<p style="text-align: right;">Page 31</p> <p>1 A. Most likely.</p> <p>2 Q. Okay. Would this indicate to you</p> <p>3 approximately the time that you would have been</p> <p>4 retained in the Wave 1 --</p> <p>5 A. I wouldn't use the word "retained". I think</p> <p>6 our Wave 1 discussions and conversations started in or</p> <p>7 around the 1st of January.</p> <p>8 Q. So is it fair to say that all of the invoices</p> <p>9 after January 21st, 2016 would relate to the work that</p> <p>10 you conducted in the Wave 1 litigation?</p> <p>11 A. No, not necessarily. Actually, I take that</p> <p>12 back. With regards to this project number, yes.</p> <p>13 Q. Okay. So Project No. 1504469 would -- would</p> <p>14 represent the project number for the Wave 1 work?</p> <p>15 A. And -- and Mullins, correct.</p> <p>16 Q. Okay. So January 21st, 2016 is an invoice,</p> <p>17 again, for \$6,078. The next invoice is a month later;</p> <p>18 approximately February 23rd, 2016. It's not totaled,</p> <p>19 but would be somewhere between 30- and \$40,000?</p> <p>20 A. Approximately.</p> <p>21 Q. The next invoice I have is March 16th, 2016.</p> <p>22 Again, this invoice is not totaled, but it would appear</p> <p>23 to be somewhere north of -- somewhere close to a</p> <p>24 hundred thousand?</p>	<p style="text-align: right;">Page 33</p> <p>1 Q. Yeah. There would be additional billing,</p> <p>2 right?</p> <p>3 A. Yeah. Sure.</p> <p>4 Q. Okay. And what work has been conducted by</p> <p>5 you or Exponent related to the Wave 1 cases since the</p> <p>6 March 15th, 2016 invoice? If you know.</p> <p>7 A. I don't think I know specifically, without</p> <p>8 looking at the -- I would say the pending or the</p> <p>9 current invoices which have not been generated yet. I</p> <p>10 suspect some of them would have been related to my</p> <p>11 deposition prep.</p> <p>12 Q. And how much time have you spent prepping for</p> <p>13 the deposition?</p> <p>14 A. I don't -- I don't know a number.</p> <p>15 Q. 20 hours or more?</p> <p>16 A. I think, yeah, probably 20 to 30 hours.</p> <p>17 Q. And does that include prep that you've --</p> <p>18 strike that.</p> <p>19 Does that include meetings that you've held</p> <p>20 or had with Ethicon's counsel in preparation for the</p> <p>21 deposition?</p> <p>22 A. Yes, that would include that.</p> <p>23 Q. Okay. And when did you meet with Ethicon's</p> <p>24 counsel to prepare for the deposition?</p>

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<p>1 A. Dr. -- excuse me. Mr. Thomas and I met last 2 night for a few hours.</p> <p>3 Q. How many hours did you meet last night to 4 prepare for the deposition?</p> <p>5 A. Probably two.</p> <p>6 Q. We're done with the invoices. Just keep 7 those invoices together, because they're a composite 8 exhibit.</p> <p>9 Doctor, I'm going to go ahead and mark my 10 copy of your expert report, the primary expert report 11 that was issued in Wave 1, as Exhibit No. 14. (MacLean Deposition Exhibit 14 - Copy of 13 Expert Report of Dr. Steven MacLean - marked 14 for identification.)</p> <p>15 Q. I've remarked it just so that we could 16 navigate easier, because I've got my own marked-up 17 copy, so.</p> <p>18 But your Wave 1 expert report, if you turn to 19 the -- maybe the first page, it shows a date of 20 March 1st, 2016.</p> <p>21 A. Correct.</p> <p>22 Q. Okay. And is that -- to your recollection, 23 is that when you had finished and signed your Wave 1 24 first report? Approximately.</p>	<p>1 supplemental report did not conclude until, you said, 2 early March?</p> <p>3 A. Yeah. I can give you a date.</p> <p>4 Q. I'll go ahead and -- let's mark as Exhibit 5 No. 15 my copy of your supplemental report. (MacLean Deposition Exhibit 15 - Copy of the 7 Supplemental Report by Steven MacLean - 8 marked for identification.)</p> <p>9 Q. Your supplemental report is dated March 22nd, 10 2016?</p> <p>11 A. Correct.</p> <p>12 Q. And the reason why you couldn't submit it 13 earlier was because the work that you were conducting, 14 which is contained within the supplemental report, 15 wasn't yet complete.</p> <p>16 A. Correct.</p> <p>17 Q. Were you provided with a deadline for 18 which the work needed to be completed for the Wave 19 1 cases?</p> <p>20 A. No. I was not given a deadline.</p> <p>21 Q. And the work that you -- that is reported in 22 your supplemental report, the additional analysis of 23 the TVT products, the hernia product, and the suture 24 product, when did you begin that work?</p>
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<p>1 A. I don't recall, but I'll take the date at 2 face value.</p> <p>3 Q. Okay. And we're not going to spend a whole 4 lot of time on your first report, because it's -- 5 contains a lot of the same information and testimony 6 that you had provided in the Mullins case. Okay?</p> <p>7 A. (Witness nods head.)</p> <p>8 Q. We may -- we might jump to it, but we're not 9 going to spend too much time on it.</p> <p>10 A. Understood.</p> <p>11 Q. And after you had submitted your initial 12 report in Wave 1, you then submitted a supplemental 13 report, correct?</p> <p>14 A. Correct.</p> <p>15 Q. And the supplemental report was submitted 16 late, after the deadline for expert disclosures? Do 17 you --</p> <p>18 A. I don't recall those dates. I can only go 19 with what date was on the actual report.</p> <p>20 Q. Why weren't you able to submit your 21 supplemental report earlier?</p> <p>22 A. Because the work that we were performing did 23 not conclude, I think, until early March.</p> <p>24 Q. So the work that is contained within your</p>	<p>1 A. Off memory, in and around February 1st, 2016.</p> <p>2 Q. And why don't you just briefly describe what 3 additional experiments you did which are contained 4 within your Wave 1 supplemental report.</p> <p>5 A. Okay. So we sought to expand the previous 6 work that we did. And so I acquired a number of 7 different PROLENE products. As you mentioned, a TVT 8 mesh, hernia mesh, PROLENE sutures. We also went out 9 in the open market and bought an off-the-shelf grade of 10 polypropylene from Sigma-Aldrich. And we deliberately 11 oxidized those specimens under two defined protocols. 12 And then after we oxidized them, they were microtomed 13 and stained in H&E staining solutions. And we then did 14 some microscopy work to determine if the stain was 15 retained by any of those specimens.</p> <p>16 Q. Okay. If we turn to Page 4 of your 17 supplemental report, Exhibit No. 15, you have sort of 18 the introduction of your report. Page 4. I'm sorry, 19 Exhibit No. 15.</p> <p>20 MR. THOMAS: That's the wrong one.</p> <p>21 Q. There you go. Okay. (Discussion held off the record.)</p> <p>22 (Attorney Joseph Kramer joins deposition by 23 teleconference.)</p>

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<p>1 Q. Back to Exhibit No. 15, Page 4, you sort of 2 summarize the additional testing or materials that you 3 analyzed for your supplemental report. Correct?</p> <p>4 A. That is correct.</p> <p>5 Q. And so it looks like you looked at three TVT 6 samples, one hernia sample, and one suture sample. 7 Correct?</p> <p>8 A. Correct.</p> <p>9 Q. Okay. And you conducted additional -- an 10 additional experiment using the QUV oxidation. 11 Correct?</p> <p>12 A. Correct.</p> <p>13 Q. Which is UV radiation, right?</p> <p>14 A. It is.</p> <p>15 Q. You intentionally oxidized the -- or your 16 intent was to intentionally oxidize the samples using 17 UV light?</p> <p>18 A. Correct.</p> <p>19 Q. And energy?</p> <p>20 A. We irradiated the samples with UV light, 21 correct.</p> <p>22 Q. And you accelerated that -- that by 23 increasing the temperature?</p> <p>24 A. It was 60 degrees Celsius inside the chamber.</p>	<p>1 prepared for these experiments, and a section of 2 approximately one centimeter?</p> <p>3 A. It says each sample that was cut was 4 approximately one centimeter in length.</p> <p>5 Q. Okay. So from each product --</p> <p>6 A. Yep.</p> <p>7 Q. -- for the QUV/UV oxidation experiment, how 8 many pieces were cut to conduct that experiment of each 9 of those products; the TVT, the hernia mesh, and the 10 suture?</p> <p>11 A. That were exposed to QUV?</p> <p>12 Q. Yeah.</p> <p>13 A. So I have one swath of material from Device 14 3859228. A second one, second swath of material from 15 3859228.</p> <p>16 Q. What product is 389228 [sic]?</p> <p>17 A. TVT device.</p> <p>18 Q. Okay. And then it's --</p> <p>19 MR. THOMAS: It's the lot number in the 20 paragraph, Dan.</p> <p>21 A. Yeah. And then there's a second mesh from 22 that same lot, which we took out two swaths.</p> <p>23 Q. And when you say "swaths", are you talking 24 about the one-centimeter sample?</p>
Page 39	Page 41
<p>1 Q. Okay. And how many pieces of the TVT device 2 were subjected to the UV irradiation experiment?</p> <p>3 A. There were several hundred individual fibers 4 that were exposed to QUV.</p> <p>5 Q. How many samples of the -- so I'm just trying 6 to break this down. Okay?</p> <p>7 A. Sure.</p> <p>8 Q. You received three TVT pristine, 9 in-the-package products from Ethicon. Correct?</p> <p>10 A. (No response.)</p> <p>11 Q. If you turn to Page 9 -- maybe this will help 12 you out. If you turn to Page 9 of your supplemental 13 report.</p> <p>14 A. (Witness complies.)</p> <p>15 Q. You talk about sample preparation.</p> <p>16 A. Correct.</p> <p>17 Q. Okay. And it says that from each of the TVT 18 products, the hernia mesh product, and the suture, 19 somebody from Exponent used a razor blade to cut about 20 a one-centimeter-long section -- or sections of each 21 sample. Do you see that?</p> <p>22 A. I do.</p> <p>23 Q. Okay. So is it fair to say that for each of 24 these devices or products, one section was cut and</p>	<p>1 A. That's right. A region of the mesh that was 2 excised out. Each one of those swaths contains up -- 3 on the upwards of 200 individual fibers.</p> <p>4 And then we have two -- two swaths that were 5 excised from TVT device, Lot No. 3832826. We have a 6 swath excised from hernia mesh Lot No. 27770-20. And a 7 second swath that was excised from that same mesh.</p> <p>8 So -- and those would be the universe of QUV 9 specimens.</p> <p>10 Q. Okay. Did you -- I thought you did some QUV 11 on the suture 6-0.</p> <p>12 A. Right. I was just talking about mesh.</p> <p>13 Q. Okay. Did you also do UV radiation on the 14 PROLENE sutures?</p> <p>15 A. Yes.</p> <p>16 Q. How many swaths?</p> <p>17 A. Appears to be 15 sutures.</p> <p>18 Q. 15 sutures?</p> <p>19 A. (Witness nods head.)</p> <p>20 Q. Okay. And were -- so let me try to summarize 21 how many samples were exposed to UV radiation on the 22 QUV experiment.</p> <p>23 As I understand it, there were four -- what 24 you call swaths of the TVT.</p>

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<p style="text-align: right;">Page 42</p> <p>1 A. Correct. 2 Q. Correct? There were four swaths from the 3 hernia. 4 A. I have six swaths from TVT and two additional 5 ones from hernia. 6 Q. Okay. So six from TVT, two from hernia, and 7 then 15 individual sutures? 8 A. I believe so. 9 Q. And based on your report, these samples were 10 exposed to QUV radiation for a period of five to 12 11 days? 12 A. Correct. 13 Q. And then they were analyzed by you or 14 somebody at Exponent using scan electron microscopy? 15 A. They were. Their surfaces -- surface 16 topography and morphology was monitored through SEM. 17 Q. Okay. Who monitored the surface morphology? 18 A. Dr. Lyons. 19 Q. Okay. Who -- 20 A. L-Y-O-N-S. 21 Q. Okay. So Dr. Lyons was conducting the SEM 22 imaging or analysis during the QUV oxidation 23 experiment. 24 A. Correct.</p>	<p style="text-align: right;">Page 44</p> <p>1 fibers. 2 Q. Okay. And Histon was asked to do what? 3 A. They were asked to perform the staining 4 portion of the work. 5 Q. And Histon is the same pathology company 6 that you and Exponent used in the Mullins case? 7 A. Correct. 8 Q. Have you ever used Histon for any other work 9 prior to Mullins? 10 A. I have not. Exponent has. 11 Q. How did you learn about Histon? 12 A. Through Dr. Garcia. 13 Q. So Dr. Garcia recommended to you Histon as 14 the laboratory to conduct the processing and staining 15 of -- of these samples. Is that correct? 16 A. Yes. I asked her to identify a lab that had 17 this expertise, and that's the lab she mentioned. 18 Q. And how were the -- how did Histon -- strike 19 that. 20 How many of the samples that we just 21 discussed were sent to Histon for paraffin embedding? 22 A. Oh, it was roughly half. About half went 23 into paraffin, and about half went into the resin. 24 Q. Is there a document that would identify for</p>
<p style="text-align: right;">Page 43</p> <p>1 Q. And after the five to 12 days, after the 2 morphology or the cracking started to appear on the 3 surface of the material, you did some additional 4 analysis using FTIR? 5 A. Correct. 6 Q. And you did some additional SEM EX? Is that 7 correct? 8 A. Correct. 9 Q. And then at some point some of these samples 10 were submitted for histology preparation. 11 A. All of -- it's all from the same universe of 12 specimens. So after they came out of the QUV chamber, 13 a small section was excised off of one of the corners 14 of the mesh, and that was analyzed through the FTIR 15 technique that you just described. And the remainder 16 of that specimen was sent off to histology. 17 Q. Okay. So how many samples were sent to 18 histology? 19 A. All of them. 20 Q. Okay. So all -- so the six sutures -- I'm 21 sorry. Strike that. The six TVT's, the two hernia 22 samples, and the 15 sutures were sent to a third-party 23 company called Histon? 24 A. Right. Which contained 7- to 800 individual</p>	<p style="text-align: right;">Page 45</p> <p>1 me -- I don't need you -- 2 A. Yeah. 3 Q. Just for later on, if I want to go and find 4 out how many pieces of samples were embedded in 5 paraffin by Histon, is there a document I can look to, 6 to find that out? 7 A. If you look at all of the -- two things. You 8 can look at the log. The log may contain that 9 information. But if you look at the file names of all 10 the micrographs, if you see a capital "P", that stands 11 for paraffin. If you see an isolated capital "R", that 12 stands for resin. 13 Q. Okay. So -- so roughly half of these samples 14 were submitted -- or were embedded into paraffin by 15 Histon. Right? 16 A. Correct. 17 Q. And what protocol did you instruct Histon to 18 use in embedding these samples in paraffin? 19 A. The protocol that's listed in my report. So 20 if you look at it on the thumb drive -- I know you 21 don't have it. I'll just speak to -- speak to it, so 22 it's on the record. 23 Q. I may -- I may have it. I have a protocol 24 here. Is that what you're referring to?</p>

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<p style="text-align: right;">Page 46</p> <p>1 A. I am. 2 MR. THOMAS: There's several protocols. 3 A. Yeah, there's several. But this one's 4 entitled Histology, Embedding, and Staining Protocol 5 for PROLENE Mesh and Sutures. 6 Q. You didn't -- when we -- when I took your 7 deposition in Mullins, you didn't have any written 8 protocols. 9 MR. THOMAS: Object to the form. 10 A. Sure, we did. 11 Q. You didn't produce any protocols. 12 A. These -- this staining protocol's in my 13 report, in the Mullins report. 14 Q. Okay. Let's go ahead and mark as Exhibit 15 No. -- 16 (Discussion held off the record.) 17 (Recess held from 9:50 a.m. till 9:53 a.m.) 18 (MacLean Deposition Exhibit 16 - Histology, 19 Embedding, and Staining Protocol for PROLENE 20 Mesh and Sutures - marked for 21 identification.) 22 BY MR. THORNBURGH: 23 Q. Okay, Doctor, I'm going to hand you what I've 24 marked as Exhibit No. 16, which appears to be -- or is</p>	<p style="text-align: right;">Page 48</p> <p>1 MR. THOMAS: Object to form. 2 A. Our reports are formal. 3 Q. There wasn't a formal Exponent document 4 protocol. 5 MR. THOMAS: Object to form. 6 Q. Other -- other than what was contained within 7 your expert report. Right? 8 A. The expert report contains the protocol that 9 we use. 10 Q. In any event, after I took your deposition in 11 the Mullins case, this document, Exhibit No. 16, was 12 created. 13 A. Correct. 14 Q. All right. And this is -- and the intent of 15 this document is to have a protocol that can be 16 followed by you or -- or individuals at Exponent so 17 that you can follow the steps appropriately. Right? 18 A. That's what the protocol is used for. 19 Q. And it says -- under "Purpose", it says, "The 20 purpose of this document is to describe histology, 21 embedding, and staining procedures for PROLENE mesh and 22 suture material." 23 Did I read that correctly? 24 A. You did.</p>
<p style="text-align: right;">Page 47</p> <p>1 labeled the Laboratory Protocol for Histology, 2 Embedding, and Staining Protocol for PROLENE Mesh and 3 Sutures. 4 (Discussion held off the record.) 5 Q. Doctor, do you recognize Exhibit 16? 6 A. I do. 7 Q. Okay. And is Exhibit 16 the written protocol 8 for paraffin embedding and staining? 9 A. It is. 10 Q. Okay. And when was this protocol first 11 written? 12 A. This particular document was written on 13 January 19th, 2016. 14 Q. Okay. And that would have been after your 15 Mullins deposition, correct? 16 A. This document, correct. 17 Q. Okay. So there wasn't an actual laboratory 18 protocol like the one that we have here as Exhibit 16 19 that was written out by Exponent and produced to me in 20 that litigation. Correct? 21 A. I disagree. Appendix A of my September 10th, 22 2015 report has histology protocols in it. 23 Q. There wasn't a formal Exponent document, 24 correct?</p>	<p style="text-align: right;">Page 49</p> <p>1 Q. Okay. If you go down to Section C, it says 2 "Paraffin-Embedding Protocol". 3 A. Yes. 4 Q. Okay. And it says -- under Section C, it 5 says -- there's a -- well, strike that. 6 It says "Paraffin-Embedding Protocol", and 7 there's a Footnote No. 1. Which if you go to the 8 Footnote No. 1, it says, "Paraffin-embedded samples are 9 prepared and stained following the protocol submitted 10 by Dr. Iakovlev." 11 Did I read that correctly? 12 A. You read the footnote correctly. 13 Q. So what was the purpose of creating a 14 paraffin-embedding protocol that would follow the 15 protocol submitted by Dr. Iakovlev? 16 A. We were attempting to replicate his work on 17 non-explanted mesh and PROLENE materials. 18 Q. Okay. So your goal was to attempt to 19 reproduce the results of Dr. Iakovlev. Is that 20 correct? 21 A. No, that's not correct. Not his results. We 22 were just performing the control study which his 23 experiments were missing. 24 Q. Okay. So it's your testimony that your</p>

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<p style="text-align: right;">Page 50</p> <p>1 purpose was to see if his study was reproducible --</p> <p>2 A. No.</p> <p>3 Q. -- in your control.</p> <p>4 A. No. That's not what we tried to do. Mr. --</p> <p>5 Dr. Iakovlev's experiment was on explanted materials.</p> <p>6 His experiments lacked a control in known oxidized</p> <p>7 material exposed to staining, and so we simply filled</p> <p>8 that gap. We didn't try to reproduce what he did. It</p> <p>9 was a fundamental step missing from his experiments</p> <p>10 that we filled with our control experiment.</p> <p>11 Q. So it was important for your control</p> <p>12 experiment, since it's a control, to follow the</p> <p>13 protocol that was outlined by Dr. Iakovlev.</p> <p>14 A. Correct.</p> <p>15 Q. And who provided to you the protocol of</p> <p>16 Dr. Iakovlev?</p> <p>17 A. I believe it came in some form from all the</p> <p>18 production documents. I don't remember where it came</p> <p>19 from.</p> <p>20 Q. I didn't -- I looked through the materials</p> <p>21 that were produced, and I didn't see any written</p> <p>22 protocol of Dr. Iakovlev within the documents you</p> <p>23 produced. Maybe I'm missing it. I'm not suggesting</p> <p>24 that --</p>	<p style="text-align: right;">Page 52</p> <p>1 results.</p> <p>2 MR. THOMAS: Object to form.</p> <p>3 A. I'd need more information to pass judgment on</p> <p>4 that.</p> <p>5 Q. Your intent was to follow Dr. Iakovlev's</p> <p>6 protocol.</p> <p>7 MR. THOMAS: Object to form.</p> <p>8 A. Our intent was to stain deliberately oxidized</p> <p>9 specimens from a well-accepted H&E process, correct.</p> <p>10 Q. As a control.</p> <p>11 A. As a control.</p> <p>12 Q. And if you're doing a control, it's important</p> <p>13 for you to follow the procedures and protocol of</p> <p>14 Dr. Iakovlev.</p> <p>15 MR. THOMAS: Object to form.</p> <p>16 Q. Right?</p> <p>17 A. We did a control experiment with H&E stains.</p> <p>18 That's what we did; oxidized specimens that were then</p> <p>19 ultimately stained with H&E.</p> <p>20 (Witness asked for clarification by the</p> <p>21 reporter.)</p> <p>22 A. We did an experiment with intentionally</p> <p>23 oxidized specimens that were ultimately H&E stained.</p> <p>24 Q. Well, the purpose of a control is that you</p>
<p style="text-align: right;">Page 51</p> <p>1 A. Yeah. I don't -- I don't recall off the top</p> <p>2 of my head what production document that came from or</p> <p>3 where we found it, for that matter. I just don't</p> <p>4 recall.</p> <p>5 Q. Do you know when you received it?</p> <p>6 A. Well, we certainly had it before the first</p> <p>7 round of work. So sometime last summer, last fall.</p> <p>8 Q. Okay.</p> <p>9 A. He may have referenced something that was</p> <p>10 publicly available, and that's what we used. I just --</p> <p>11 I just don't recall.</p> <p>12 Q. Okay. But your -- your goal was to follow</p> <p>13 the same protocol that Dr. Iakovlev has -- had used.</p> <p>14 Right?</p> <p>15 A. Yes. That was our intent; to basically do</p> <p>16 the same type of staining that he did; embedding and</p> <p>17 staining that he did.</p> <p>18 Q. And if you don't follow the protocol of</p> <p>19 Dr. Iakovlev, your conclusions could be inaccurate.</p> <p>20 MR. THOMAS: Object to form.</p> <p>21 A. I think you'd have to show me what you mean</p> <p>22 by "different".</p> <p>23 Q. If you didn't follow the protocol of</p> <p>24 Dr. Iakovlev, that could call into question your</p>	<p style="text-align: right;">Page 53</p> <p>1 treat the control the same way that you treat the</p> <p>2 experimental material. Right?</p> <p>3 A. Correct. We make every attempt to follow the</p> <p>4 procedure that was outlined in our protocol.</p> <p>5 Q. And if you don't, you have an invalid</p> <p>6 control.</p> <p>7 A. No, not necessarily.</p> <p>8 MR. THOMAS: Object to form.</p> <p>9 A. Not necessarily. You'll need to give me more</p> <p>10 information if you --</p> <p>11 Q. I'm just trying to get some background</p> <p>12 information.</p> <p>13 A. Asked and answered.</p> <p>14 Q. Well, let's look at Exhibit -- let's look at</p> <p>15 Exhibit 16, Paraffin-Embedding Protocol. And you say</p> <p>16 that your -- you prepared this protocol following the</p> <p>17 protocol of Dr. Iakovlev. And then if you look at the</p> <p>18 very -- No. 1, it says you process and embed samples in</p> <p>19 an automated tissue processor according to the</p> <p>20 following schedule. Did I read that correctly?</p> <p>21 A. I'm sorry, what page are you on?</p> <p>22 Q. Page 1, Exhibit 16.</p> <p>23 A. Um-hum.</p> <p>24 Q. Section C.</p>

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<p>1 A. Yep.</p> <p>2 Q. Where you are laying out the protocol for</p> <p>3 paraffin embedding. And you have a set of steps,</p> <p>4 right? 1 through 6?</p> <p>5 A. Correct.</p> <p>6 Q. And the first step is 70 percent reagent</p> <p>7 alcohol; number of changes, two; one hour each. Right?</p> <p>8 A. Correct.</p> <p>9 Q. Okay. And what was the purpose of doing that</p> <p>10 step?</p> <p>11 A. Those are just dehydration steps.</p> <p>12 Q. Now, there's no tissue, right?</p> <p>13 A. There is no tissue.</p> <p>14 Q. So there's no tissue on your samples. Right?</p> <p>15 A. No. They're control specimens.</p> <p>16 Q. Okay. So you're not really dehydrating</p> <p>17 tissue.</p> <p>18 A. No, but we're following a standard embedding</p> <p>19 procedure. So we didn't want to leave any steps out.</p> <p>20 Q. You didn't want to leave any steps out.</p> <p>21 A. Correct.</p> <p>22 Q. It's important to follow the steps.</p> <p>23 A. Sure.</p> <p>24 Q. Okay. If you go to Step 2, 80 percent</p>	<p>1 solvent that's part of the protocol.</p> <p>2 Q. What was the purpose of using xylene in Step</p> <p>3 4 -- or Step 5?</p> <p>4 A. Probably just -- additional dehydration, if</p> <p>5 not alcohol removal, residual alcohol removal.</p> <p>6 Q. Okay. And then Step 6 is the Lerica</p> <p>7 paraffin waxing; is that correct?</p> <p>8 A. Leica, correct.</p> <p>9 Q. Leica. And why did you have Leica here?</p> <p>10 A. It's just the brand name.</p> <p>11 Q. Okay. Is that the same brand that was used</p> <p>12 by Dr. Iakovlev?</p> <p>13 A. I don't recall, and it wouldn't matter,</p> <p>14 because that paraffin goes away after you go through</p> <p>15 the entire process.</p> <p>16 Q. Okay. So --</p> <p>17 A. Just -- the paraffin's just used to hold the</p> <p>18 specimen in place during the microtoming.</p> <p>19 Q. So, so far, your control, you've done</p> <p>20 dehydration, and then you've added some -- you've done</p> <p>21 the paraffin waxing. Right?</p> <p>22 MR. THOMAS: Object to form.</p> <p>23 A. In between there, there's the xylene</p> <p>24 substitute step. But, yes.</p>
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<p>1 reagent alcohol. Right?</p> <p>2 A. Um-hum.</p> <p>3 Q. What was the purpose of that? Additional</p> <p>4 dehydration?</p> <p>5 A. Correct.</p> <p>6 Q. And number of changes, one, for one hour.</p> <p>7 A. Correct.</p> <p>8 Q. Okay. If you go to Step 3, 95 percent</p> <p>9 reagent alcohol; number of changes, one, for another</p> <p>10 hour. Right?</p> <p>11 A. Correct.</p> <p>12 Q. And this is all going to be -- all these</p> <p>13 steps are going to be performed by Histon, right?</p> <p>14 A. That's right.</p> <p>15 Q. Exponent didn't have any role in</p> <p>16 performing these --</p> <p>17 A. We oversaw --</p> <p>18 Q. -- steps --</p> <p>19 A. Excuse me. We oversaw the work.</p> <p>20 Q. Step 4 is another dehydration. Right?</p> <p>21 A. It is.</p> <p>22 Q. Step 5, it says, "Xylene substitute (ProPar,</p> <p>23 Manufacturer)." What's that?</p> <p>24 A. It's just part of the protocol. Xylene is a</p>	<p>1 Q. Okay. And you said that at some point the</p> <p>2 wax -- the paraffin wax gets removed through the steps</p> <p>3 in the protocol.</p> <p>4 A. Correct.</p> <p>5 Q. And that's important to remove the wax,</p> <p>6 right?</p> <p>7 A. It's a by-product of the process. You're</p> <p>8 trying to -- you're ultimately trying to isolate the</p> <p>9 fibers. So, yes.</p> <p>10 Q. What would happen if you didn't remove all</p> <p>11 the wax? Before you tried to stain.</p> <p>12 A. I don't know, because we didn't have that</p> <p>13 issue. The paraffin was removed.</p> <p>14 Q. You don't know what would -- or how the</p> <p>15 staining of your samples would be compromised if you</p> <p>16 didn't remove the wax?</p> <p>17 A. I'm telling you I don't know because it</p> <p>18 didn't happen.</p> <p>19 Q. I'm just -- I'm trying to understand. Do you</p> <p>20 have an understanding of the importance of removing the</p> <p>21 wax?</p> <p>22 A. I don't know if I'd classify it as important.</p> <p>23 It just happens during the process.</p> <p>24 Q. You don't --</p>

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<p>1 A. So if you think about it, the paraffin is on 2 the outside of the fiber. We're staining a 3 cross-section. Right? So the cross-section is not 4 influenced or in contact with the paraffin itself. 5 That's actually an encasement around the outside of the 6 fiber. You would be staining a pristinely cut, if you 7 will, cross-section which has no paraffin on it. So I 8 don't -- I don't understand what you're getting at. 9 Q. Well, if the mesh was -- if the fibers were 10 oxidized and cracked, right, that's not -- it's not 11 cracked in the cross-section. It's cracked around the 12 fibers on the outer layer. 13 A. Correct. 14 Q. Where the -- where the wax is going to be 15 located. Right? 16 A. Right. 17 Q. Okay. So do you have an understanding of the 18 importance of deparaffinizing these samples? 19 A. I have an understanding that the paraffin is 20 removed from the process. 21 Q. How could the failure to remove the paraffin 22 wax compromise the staining? 23 A. I would argue that it may not compromise the 24 staining, because I have a freshly cut cross-section of</p>	<p>1 is a cross-section of the specimen. The paraffin is on 2 the outside. So all of the cross-sectional area that 3 we've now produced from the microtoming process is 4 inboard from the paraffin. 5 Q. If you look at No. 2, it says, "Embed samples 6 in paraffin blocks using Leica." Do you see that? 7 A. I do. 8 Q. And you go down through these sections until 9 you get to Section D. Strike that. 10 "Trim the paraffin blocks, as necessary, and 11 cut a 4-6 micron-thick sections [sic]." 12 "Briefly float the paraffin sections in a 13 water bath set to 40-45 degrees Celsius to remove 14 wrinkles and allow them to flatten." 15 Do you understand what the purpose of that 16 step is? 17 A. Step No. 4? 18 Q. Yeah. 19 A. Yes. 20 Q. What is the purpose of that step? 21 A. To make it as flat as possible after floating 22 in the water. 23 Q. Step 5 says, "Mount the sections onto 24 adhesive-coated glass slides, then air dry for 30</p>
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<p>1 all available material that has never been in contact 2 with the pristine material, aside from what might have 3 come in from the cracks. But I still have a layer of 4 material that would not have been in contact, direct 5 contact with the paraffin. So I don't understand your 6 question. 7 Q. You're not a pathologist, are you? 8 A. I never said I was a pathologist. 9 Q. You don't hold yourself out as an expert in 10 pathology. Right? 11 A. Correct. I do not study tissue. 12 Q. You don't know, sitting here right now, how a 13 failure to deparaffinize these samples could compromise 14 the staining in your study. 15 A. It won't compromise -- first of all, it 16 didn't happen. And, second of all, it won't compromise 17 my specimens for the reason I just described to you. 18 Q. It's your opinion that it wouldn't compromise 19 the specimens if the paraffin wax is not adequately 20 removed. 21 MR. THOMAS: Object to form. 22 A. Look, there is no evidence that there was 23 insufficient removal of paraffin in our specimens. And 24 what I'm telling you is the material that gets stained</p>	<p>1 minutes and bake in a 45-50 degree oven overnight." 2 Correct? 3 A. That's what it says. 4 Q. What is the purpose of that? 5 A. Just to drive off any excess moisture. 6 Q. The next section is a staining protocol for 7 paraffin-embedded samples. Right? 8 A. Um-hum. Correct. 9 MR. THOMAS: Did you say standing? 10 MR. THORNBURGH: Staining. 11 Q. And so this is the section of the protocol 12 where the mesh becomes stained. Right? Or the samples 13 become stained. 14 A. Yes. There's -- there's some additional 15 preparation steps to take on the staining, and then 16 ultimately the staining, yes. 17 Q. Okay. And it says, "Stain samples using an 18 automated stainer programmed with the following 19 protocol." 20 A. Correct. 21 Q. Do you know what automated stainer program is 22 used? 23 A. Not off the top of my head. It might be in 24 the files somewhere.</p>

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<p>1 Q. In fact, if you were following Dr. Iakovlev's 2 protocol, his protocol calls for manual staining. 3 Correct?</p> <p>4 A. Correct.</p> <p>5 Q. All right. You did not follow 6 manual-staining protocol.</p> <p>7 A. No, we actually did. We ultimately chose to 8 go manual in the second round.</p> <p>9 Q. So you deviated from your protocol?</p> <p>10 MR. THOMAS: Object to form.</p> <p>11 A. We did. We determined that the automated 12 stainer was a bit too aggressive and abusive, and we 13 were -- we were losing some of the specimens during the 14 staining process. So we felt like it would be -- 15 because the specimens are so delicate, that it would be 16 in our best interests to do hand-staining.</p> <p>17 Q. How many of -- how many of your samples, the 18 QUV -- yeah, UV-oxidized samples were -- went through 19 the automatic or automated staining process?</p> <p>20 A. In this round, none.</p> <p>21 Q. And which round are you referring to?</p> <p>22 A. The Wave 1 supplemental work. None of them 23 went through the automated process.</p> <p>24 Q. So the Mullins samples did?</p>	<p>1 let's do manual staining next time.</p> <p>2 Q. Okay. And so you decided to no longer do the 3 automated staining.</p> <p>4 A. Correct.</p> <p>5 Q. And then you draft this protocol dated 6 January 19th, 2016, after your deposition in Mullins, 7 after the work that you performed in Mullins. And in 8 your written protocol that was drafted after your 9 experience with the automated staining, you write in 10 your protocol that Histon needs to use an automated 11 stainer.</p> <p>12 A. Yes. But you're misinterpreting it. It's 13 simply for efficiency and productivity. There's 14 nothing wrong with either processes -- hold on. Let me 15 answer my -- let me answer your question. There is 16 nothing wrong with either one. We just wanted to be 17 more efficient with how many survived the staining 18 process.</p> <p>19 There is nothing wrong or -- you don't get 20 poor results from automatic staining. We just felt 21 like we could be more efficient and have more slides 22 survive the staining process if we did it manually. 23 That's all. It was just a productivity discussion; no 24 more, no less.</p>
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<p>1 A. Correct.</p> <p>2 Q. And you determined in Mullins that the 3 automated stainer was too aggressive, and so it's your 4 testimony that after Mullins, you decided to go from 5 the automated staining to the manual staining.</p> <p>6 A. Correct. And let me clear the record up on 7 what I meant by "aggressive". The specimens just were 8 not staying on the slides as well as we would have 9 liked because of all the movement. And we just felt 10 like a more delicate procedure by hand would allow us 11 to maintain more specimens on the slides.</p> <p>12 Q. Okay. So you testified in the Mullins 13 litigation after you had already conducted the work.</p> <p>14 A. Correct. Yes.</p> <p>15 Q. You had already conducted the work, you had 16 already experienced what you called the aggressive 17 automatic staining. So you, before your deposition, 18 already knew that automated staining would be 19 inappropriate.</p> <p>20 MR. THOMAS: Object to form of the question.</p> <p>21 A. No. We would -- no, I would not characterize 22 it as inappropriate. It was a discussion we had 23 following -- just in follow-up to our Mullins work. I 24 don't remember when it was. But we just said, hey,</p>	<p>1 Q. But what you're telling me doesn't make 2 sense --</p> <p>3 A. Sure it does.</p> <p>4 Q. -- from -- chronologically. Okay? So in 5 Mullins --</p> <p>6 A. There's nothing chronological about it.</p> <p>7 Q. Let me finish my question.</p> <p>8 A. Go ahead.</p> <p>9 Q. Okay? In the Mullins litigation, you 10 performed some work using automated staining.</p> <p>11 A. Correct.</p> <p>12 Q. You determined that the automated staining 13 was too aggressive to the samples.</p> <p>14 MR. THOMAS: Object to form.</p> <p>15 Q. Right?</p> <p>16 A. It was not giving us the right amount of 17 samples at the end of the day. Some of them were 18 falling off.</p> <p>19 Q. You decided in Mullins not to use the 20 automated stainer anymore.</p> <p>21 MR. THOMAS: Object to form.</p> <p>22 A. Incorrect. Not during Mullins.</p> <p>23 Q. Or after Mullins.</p> <p>24 A. Sometime after Mullins, correct.</p>

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<p style="text-align: right;">Page 66</p> <p>1 Q. Then you or somebody drafts this written 2 protocol after you've already gone through that 3 experience, and you have written in here that the 4 protocol needs to be done using an automated stainer.</p> <p>5 A. All correct. It was simply a reflection -- 6 before we started the second set of experiments -- 7 excuse me -- second set of experiments, we reflected on 8 what we learned from Mullins, and we said, hey, we 9 don't get a high-enough yield using the automated 10 stainer; let's just do it by hand; we think we can get 11 more specimens to survive the process. That's it.</p> <p>12 Q. Who performed the manual staining?</p> <p>13 A. Histon.</p> <p>14 Q. Who at Histon?</p> <p>15 A. Simon Smith.</p> <p>16 Q. Do you know Simon Smith?</p> <p>17 A. I've met him.</p> <p>18 Q. Is he a pathologist?</p> <p>19 A. He has done staining for decades. I don't 20 know his exact background.</p> <p>21 Q. Do you know if he's a pathologist?</p> <p>22 A. I just don't know.</p> <p>23 Q. Have you worked with Simon Smith before?</p> <p>24 A. We have.</p>	<p style="text-align: right;">Page 68</p> <p>1 Q. And then you deviated from that protocol, 2 from the Mullins protocol, and -- and had Mr. Simon 3 Smith, who's been using the automated staining program, 4 you asked him to now use a manual staining program.</p> <p>5 MR. THOMAS: Object to form.</p> <p>6 A. He was the one that performed the manual 7 staining, correct.</p> <p>8 Q. Was he the same person in Mullins who set up 9 the automated staining program?</p> <p>10 A. He was.</p> <p>11 Q. Do you know how comfortable Mr. Simon -- or 12 Mr. Smith would have been going from what he performs 13 in his laboratory, the automated -- automatic staining 14 program to manual staining?</p> <p>15 A. He didn't flinch.</p> <p>16 Q. Do you know what his experience is with doing 17 manual staining versus automatic staining?</p> <p>18 A. Yes. He says he's done it all the time.</p> <p>19 Q. Do you know -- personally, do you have any 20 knowledge of what his experience is?</p> <p>21 A. I can tell you that Histon has been staining 22 products for 25 years, and they conform to the code of 23 federal regulations in terms of their capabilities and 24 report-outs.</p>
<p style="text-align: right;">Page 67</p> <p>1 Q. You personally?</p> <p>2 A. Yes. In -- for the Mullins work.</p> <p>3 Q. But in the Mullins work, there was -- it was 4 done by the automatic staining program.</p> <p>5 A. Correct. But Simon was part of our effort. 6 He was actually leading some of the effort inside the 7 laboratory. You still have to do a lot of hands-on 8 work to follow this protocol. So he was our -- 9 basically, our main liaison, our main scientist there.</p> <p>10 Q. Okay. So automatic staining -- when 11 automatic staining is conducted, it's conducted 12 automatically. You set the program; the machine does 13 it itself.</p> <p>14 A. To a large extent.</p> <p>15 Q. So you take -- there's -- it's hands-free. 16 Hands-off.</p> <p>17 A. A portion of it is definitely hands-free.</p> <p>18 Q. That's why it's called automated. Right?</p> <p>19 A. That is correct.</p> <p>20 Q. And so Histon was set up as a laboratory 21 that routinely uses automated staining.</p> <p>22 A. I can't -- I can't say it's routinely. They 23 have an automatic stainer. They know how to use it. 24 Is was employed during our Mullins work.</p>	<p style="text-align: right;">Page 69</p> <p>1 Q. How many years have they been using automated 2 staining?</p> <p>3 A. I don't know.</p> <p>4 Q. You have no understanding, as you sit here 5 today, how many times Mr. Smith had performed manual 6 staining?</p> <p>7 A. I don't have an exact number, no.</p> <p>8 Q. You don't know, as you sit here today, what 9 his skill level was for performing the manual staining.</p> <p>10 A. I've already explained to you that this is a 11 lab that's been doing staining for 25 years. He's an 12 older gentleman with tremendous experience. I'd have 13 no doubt in my mind that he did it correctly.</p> <p>14 Q. Automated staining programs have been around 15 for 20 years.</p> <p>16 A. Show me a document that said that they've 17 been around for 20 years.</p> <p>18 MR. THOMAS: I'll have you mark as Exhibit 19 No. 17 a document entitled Automation in IHC. 20 (MacLean Deposition Exhibit 17 - Document 21 titled Automation in IHC - marked for 22 identification.)</p> <p>23 Q. So if you look at Exhibit 17 -- 24 MR. THOMAS: Did you mean to give me your</p>

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<p>1 highlighted copy?</p> <p>2 MR. THORNBURGH: No.</p> <p>3 Q. What does "automation in IHC" mean?</p> <p>4 A. Immunohistochemistry.</p> <p>5 Q. Okay. And if you turn to the first page of</p> <p>6 Chapter 17 -- of Exhibit 17, Chapter 9.1, it says</p> <p>7 "History of IHC Automation".</p> <p>8 MR. THOMAS: Is this from a textbook? Is</p> <p>9 there a title for the book, Dan, do we know?</p> <p>10 MR. THORNBURGH: Automation in IHC.</p> <p>11 MR. THOMAS: That's the chapter title. Do</p> <p>12 you know the book that it's from?</p> <p>13 MR. THORNBURGH: I don't know the title. I</p> <p>14 don't.</p> <p>15 MR. THOMAS: Okay. I'll just object to the</p> <p>16 question for that reason.</p> <p>17 Q. "History of IHC Automation". "The first --"</p> <p>18 if you look at the first paragraph, about four lines</p> <p>19 up, "The first automated device capable of both IHC and</p> <p>20 in situ hybridization (ISH) was described in 1990."</p> <p>21 A. I'm sorry, could you just tell me where you</p> <p>22 are, again.</p> <p>23 Q. Page 1 under Chapter 9.1, first paragraph.</p> <p>24 A. Um-hum. Yes.</p>	<p>1 A. Correct.</p> <p>2 Q. Do you know how long it's been in place?</p> <p>3 A. I do not.</p> <p>4 Q. Do you know when the last time Mr. Simon</p> <p>5 [sic] conducted -- or performed manual staining on any</p> <p>6 sample before he met with you to work on the Wave 1</p> <p>7 experiments?</p> <p>8 A. No. But he assured us that he's quite</p> <p>9 capable and competent of doing manual staining.</p> <p>10 Q. Were you there when he performed the</p> <p>11 staining?</p> <p>12 A. I was not there on those days. And, by the</p> <p>13 way, just as a confirmation, that's why we do positive</p> <p>14 controls. So if you look at our rabbit tissue and all</p> <p>15 of the bovine serum which we have yet to talk about yet</p> <p>16 that's around some of the specimens, they all achieved</p> <p>17 staining.</p> <p>18 So it's a moot point, in my opinion, because</p> <p>19 he clearly demonstrated that he has the capability and</p> <p>20 the expertise to do it, because all of our positive</p> <p>21 controls stained.</p> <p>22 Q. Do you know if the automated system that he</p> <p>23 was accustomed to using and used in the Mullins case</p> <p>24 prior to this -- these experiments was an open or</p>
<p style="text-align: right;">Page 71</p> <p>1 Q. Do you see there's -- see No. 4, about four</p> <p>2 lines up from the bottom.</p> <p>3 A. I do.</p> <p>4 Q. It says, "The first automated device capable</p> <p>5 of both IHC and in situ hybridization (ISH) was</p> <p>6 described in 1990." Right? Did I read that</p> <p>7 accurately?</p> <p>8 A. You did.</p> <p>9 Q. Okay. It says, "Automation quickly caught</p> <p>10 on." "Next Generation Sequencing into cancer</p> <p>11 diagnostics, and by 1995, there were several IHC</p> <p>12 instruments," (as read.) Right?</p> <p>13 A. That's what it says.</p> <p>14 Q. Okay. So the automation has been around for</p> <p>15 greater than 20 years.</p> <p>16 MR. THOMAS: Object to form.</p> <p>17 Q. Right?</p> <p>18 A. Certainly the automation stated in this</p> <p>19 literature says that.</p> <p>20 Q. Okay. And Histion was using automated</p> <p>21 staining in the Mullins case. Right?</p> <p>22 A. Correct.</p> <p>23 Q. And they have -- they have an automated</p> <p>24 staining program there. Right?</p>	<p style="text-align: right;">Page 73</p> <p>1 closed system?</p> <p>2 A. I don't recall.</p> <p>3 Q. So if we go back to the protocol, Exhibit 16,</p> <p>4 Section D where we were discussing earlier, where it</p> <p>5 says, "Stain samples using automated stainer programmed</p> <p>6 with the following protocol," that was a deviation. By</p> <p>7 going from automated to manual, that would have been a</p> <p>8 deviation of the protocol, right?</p> <p>9 MR. THOMAS: Object to form.</p> <p>10 A. We did not use an automated stainer.</p> <p>11 Q. So it would have deviated from the written</p> <p>12 protocol.</p> <p>13 MR. THOMAS: Object to form.</p> <p>14 A. We chose to go with a manual staining for the</p> <p>15 reasons -- manual staining for the reasons I already</p> <p>16 talked about.</p> <p>17 Q. And then if you look at the steps that were</p> <p>18 supposed to be programmed into the automated staining</p> <p>19 program, these steps would no longer be programmed, and</p> <p>20 now a human would be performing these steps. Right?</p> <p>21 A. A human would be performing those steps,</p> <p>22 correct.</p> <p>23 Q. Which part of this protocol describes</p> <p>24 deparaffinizing?</p>

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<p style="text-align: right;">Page 74</p> <p>1 A. These xylene steps, that's a solvent that's 2 actually going to remove the paraffin. 3 Q. So Steps 19 and 20? 4 A. No. Much earlier on. Steps 2, 3, 4. 5 Q. Sorry. I didn't see those. And you had 6 testified earlier that the deparaffinizing steps that 7 were taken -- or that were used would have been 8 sufficient for removing the paraffin wax? 9 A. Correct. 10 Q. What's your basis for that opinion? 11 A. The 25 years of experience that Histon 12 touts. And also visual observations from the 13 microscopy work. 14 Q. So it's not your personal experience. It's 15 the fact that Histon has been around for 25 years? 16 MR. THOMAS: Object to the form of the 17 question. He just said he's looked at it 18 himself. 19 A. Exactly. It's two -- the answer is two-fold. 20 One is the expertise and experience of Histon, having 21 done this type of work for decades. And, two, it's the 22 visual observation of the slides when they come out. 23 You don't see any paraffin to the outside. 24 Q. So let's talk about touting the experience of</p>	<p style="text-align: right;">Page 76</p> <p>1 for the Federal Government, because they do conform to 2 the code of federal regulations with regard to their 3 data. 4 So if someone comes to them for, say, 5 pre-clinical experimentation, their data is accepted by 6 the FDA. 7 Q. Move to strike, non-responsive. My question 8 is very simple. Histon is not a clinical pathology 9 laboratory. Correct? 10 A. Not according to their website. 11 Q. In other words, I'm correct. Right? 12 MR. THOMAS: Object to the form of the 13 question. 14 Q. I just want to make sure the record's clear. 15 A. From what I have read, correct. You can ask 16 them. They perhaps have done work that's not openly 17 marketed on their website. I don't know. That's a 18 question for them. 19 But in terms of the publicly available 20 information, what you said was correct. 21 Q. Do you know what additional federal 22 requirements are needed to run and maintain a clinical 23 pathology laboratory? 24 A. Off the top of my head, no.</p>
<p style="text-align: right;">Page 75</p> <p>1 Histon. Is Histon a laboratory that does diagnostic 2 evaluation for patient clinically -- for patients 3 clinically? 4 In other words, if someone gets a cancer, 5 develops a cancer, or they have a tumor that gets 6 removed by a surgeon, Histon is not the facility that 7 would look at and determine whether or not a patient 8 needs treatment, has cancer. 9 MR. THOMAS: Object to form. 10 Q. Right? 11 A. You're talking about histological examination 12 of tissue. There are no tissues in my specimens. So I 13 just don't understand the dots you're trying to connect 14 here. There's -- we're not doing a tissue histological 15 exam with my specimens. 16 Q. Histon is a pre-clinical laboratory. 17 A. That's correct. 18 Q. They're not a clinical laboratory. 19 A. It doesn't mean that they can't stain with 20 expertise. 21 Q. Just answer my question. Okay? Histon is 22 not a clinical laboratory. Correct? 23 A. They are not a clinical lab, correct. 24 However, their data is good enough for the Government,</p>	<p style="text-align: right;">Page 77</p> <p>1 Q. Are any of the individuals who are 2 supervising and managing Histon, are any of those 3 individuals pathologists? 4 A. I don't know. 5 Q. Do you believe that the steps that are 6 outlined under Section D are the steps and the protocol 7 that would have been used by Dr. Iakovlev? 8 A. What I can tell you is that we put what we 9 believed was Dr. Iakovlev's protocol in front of the 10 expertise and experts at Histon, and they developed 11 something that we believed would be similar, if not 12 identical, to what his steps were. That's how I can 13 answer that. 14 Q. You, sitting here right now, you don't know 15 whether or not the steps that are identified under 16 Section D followed the protocol of Dr. Iakovlev. 17 MR. THOMAS: Object to form. 18 A. I believe we've made every attempt to follow 19 what he did, based on the documentation that we have. 20 And, again, our positive control specimens tell us that 21 we achieved staining. I mean, that's what we're trying 22 to do here. We're trying to see if oxidized material 23 stains. Period. 24 Q. But were the slides charged or uncharged?</p>

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<p style="text-align: right;">Page 78</p> <p>1 A. Charged. 2 Q. Were the -- how was the staining conducted? 3 Was it a horizontal? Vertical? 4 A. Vertical. 5 Q. Vertical staining? 6 A. Correct. 7 Q. And you think that's consistent with the 8 protocol outlined by Dr. Iakovlev? 9 A. I don't believe his protocol mentioned the 10 orientation. But if you have a document that says 11 otherwise, let me know. 12 (MacLean Deposition Exhibit 18 - Iakovlev 13 Article on Degradation - marked for 14 identification.) 15 Q. Marked as Exhibit No. 18 the publication from 16 Dr. Iakovlev, Degradation of Polypropylene In Vivo, 17 Microscopic Analysis of Mesh Explanted from Patients. 18 Have you seen that publication before, Dr. 19 MacLean? 20 A. Yes. 21 Q. Okay. Do you see the section on Page 2 of 22 Exhibit 18 called "Staining"? 23 A. I do. 24 Q. Okay. Do you see where Dr. Iakovlev explains</p>	<p style="text-align: right;">Page 80</p> <p>1 manufacturers were placed in 10 percent buffered 2 formalin." Right? "The mesh was then sampled for 3 light microscopy at two weeks and one, two, and four 4 months in two separate experiments." 5 Did I read that correctly? 6 A. You did. 7 Q. Okay. "Tissue processing; embedding, 8 sectioning," says, "Charged coated slides." Do you see 9 that? 10 A. I do. 11 Q. And then it says, "And staining (manual and 12 [sic] horizontal tray) were carried out." 13 Did I read that correctly? 14 A. It says "manual on horizontal tray". 15 Q. Um-hum. 16 A. Correct. 17 Q. Okay. So Dr. Iakovlev's staining was 18 conducted manually on a horizontal tray. 19 A. In this publication. 20 Q. Okay. And the staining that was conducted by 21 Histon would have been -- in Mullins, it would have 22 been automated. Right? 23 A. In Mullins, correct. 24 Q. In the Wave 1 cases, it was, according to</p>
<p style="text-align: right;">Page 79</p> <p>1 the types of staining that he conducted in his studies? 2 A. (No response.) 3 Q. At the very beginning. He did H&E staining, 4 and he did additional staining using trichrome, Von 5 Kossa, and some -- do you see where I'm at? 6 A. I do. I see the paragraph, bottom right-hand 7 corner on Page 2. I believe that's what you're 8 referring to. 9 Q. Okay. You only did H&E staining, right? 10 A. Correct. 11 Q. You didn't do the Von Kossa staining. You 12 did not perform the trichrome staining. Right? 13 A. We did not. 14 Q. You did not perform the immunoparaffinized 15 staining using immunoperoxidase, right? 16 A. I did not. 17 Q. Okay. If you turn to Page 3, see the "New 18 Mesh Control"? Do you see where I'm at? 19 A. I do. 20 Q. "Portions of pristine trans --" and this is 21 the protocol that Dr. Iakovlev uses. 22 A. In -- in this publication. 23 Q. Okay. It says, "Portions of pristine 24 transvaginal sling devices of three different</p>	<p style="text-align: right;">Page 81</p> <p>1 you, it was done manually on a vertical tray -- 2 vertical standing. 3 A. Correct. 4 Q. So it was not horizontal. 5 A. Ours was not horizontal. 6 Q. Okay. And, by the way, where -- in all of 7 your materials that you've produced, where did you -- 8 where did you record the fact that the protocol wasn't 9 followed; that the -- your written protocol, Exponent's 10 written protocol was deviated from by going from 11 automated staining to manual staining? 12 (Discussion held off the record.) 13 A. Do you have a full copy of my supplemental 14 report? Is that what you handed me? 15 Q. That's what I handed you. 16 A. If you look on Page 37 of the supplemental 17 report, it is documented. I'm sorry. Page 36 and 37. 18 Item 6 on Page 36 reads, "Paraffin-embedded samples 19 were stained by hand using the following protocol." 20 And, likewise, a similar comment is on Page 37 by the 21 number four for the resin-embedded samples. 22 Q. Do you know what the -- why some pathologists 23 would use vertical staining versus horizontal staining? 24 A. The only thing I can tell you, that in the</p>

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<p style="text-align: right;">Page 82</p> <p>1 discussions that we've had with Histon, vertical 2 staining -- vertical orientation is preferred, because 3 it ensures that you get good rinsing, and the rinse 4 actually moves away from the specimen. The slide, I 5 should say. So it was just -- it's a preferred method 6 by Histon. They feel that they get a better wash from 7 that -- from that technique.</p> <p>8 Q. And what do you mean by a "better wash"?</p> <p>9 A. Well, the -- the slides are vertically 10 oriented, so gravity actually pulls or drops the wash 11 solution down over the sides of the slides and then 12 down away from the slides. So rinsing and washing is 13 facilitated by that orientation.</p> <p>14 Q. You agree with -- would agree with me that 15 the protocol that was used by Dr. Iakovlev, at least as 16 to the positioning of the slides as they're stained, 17 was different from that used by Histon.</p> <p>18 MR. THOMAS: Object to the form of the 19 question.</p> <p>20 A. Only with respect to his publication. Can 21 you show me in his reports for any of these matters 22 where he's cited horizontal orientation?</p> <p>23 Q. Did you believe, when you endeavored to 24 conduct these experiments and follow the protocol of</p>	<p style="text-align: right;">Page 84</p> <p>1 Q. And my question to you was: Based on your 2 review of the publication, Exhibit No. 18, of 3 Dr. Iakovlev, you'd agree with me that the positioning 4 of the slides for staining purposes was different.</p> <p>5 MR. THOMAS: Object to form.</p> <p>6 Q. Than the positioning used by Dr. -- by 7 Histon.</p> <p>8 MR. THOMAS: Same objection.</p> <p>9 A. Only in that publication. Not in his reports 10 with respect to any of these litigation matters.</p> <p>11 Q. Do you have any basis to believe or to 12 testify that Dr. Iakovlev used any other protocol other 13 than that used and reported in Exhibit 18, his 14 publication on degradation?</p> <p>15 A. We have no basis either way. It's not -- 16 there's no written protocol assigned with his report -- 17 associated with his reports that tell us either way.</p> <p>18 Q. Well, you said that your goal was to follow 19 the protocol of Dr. Iakovlev.</p> <p>20 A. To the best of our ability, based on what he 21 submitted for expert reports.</p> <p>22 Q. You didn't follow the protocol --</p> <p>23 A. Is that --</p> <p>24 Q. -- of Dr. Iakovlev --</p>
<p style="text-align: right;">Page 83</p> <p>1 Dr. Iakovlev, that Dr. Iakovlev performed the staining 2 vertically, rather than horizontally?</p> <p>3 A. We had no indication. From -- per reading 4 his reports.</p> <p>5 Q. Did you attempt to look at Dr. Iakovlev's 6 publications to determine what protocols Dr. Iakovlev 7 used?</p> <p>8 A. We certainly referenced them.</p> <p>9 Q. All right. And you would agree with me that 10 the protocol that Dr. Iakovlev used was different than 11 the protocol that you used, at least with respect to 12 the positioning of the slides when they were stained.</p> <p>13 A. Show me --</p> <p>14 MR. THOMAS: Object to the form of the 15 question.</p> <p>16 A. Show me the protocol in any of -- in his 17 reports that cite horizontal orientation that I would 18 have made that determination from. From his reports, 19 not a publication.</p> <p>20 Q. Listen to my question.</p> <p>21 A. Okay.</p> <p>22 Q. Okay? I mean, your goal was to follow the 23 protocol outlined by Dr. Iakovlev.</p> <p>24 A. To the best of our ability, correct.</p>	<p style="text-align: right;">Page 85</p> <p>1 A. -- an expert report?</p> <p>2 MR. THOMAS: One at a time.</p> <p>3 Q. -- as described in Dr. Iakovlev's 4 publication concerning the degradation of explanted 5 PROLENE mesh?</p> <p>6 MR. THOMAS: Object to form of the question.</p> <p>7 A. In a non-expert report, correct. (Discussion held off the record.) (Recess held from 10:45 a.m. till 10:51 a.m.)</p> <p>10 BY MR. THOMAS:</p> <p>11 Q. Okay, Dr. MacLean, why did you decide to only 12 use H&E staining and not the other staining that 13 Dr. Iakovlev has used?</p> <p>14 A. Because I think when you look at his reports, 15 he certainly suggests that the staining that's taking 16 place in his cracked bark is H&E. I know that there 17 are other stains that he used, but the one that we 18 chose to focus on was H&E.</p> <p>19 Q. Did you ever try to use any of the other 20 stains?</p> <p>21 A. We did not.</p> <p>22 Q. If you'd turn to Page 5 of Exhibit No. 18, 23 which is Dr. Iakovlev's publication.</p> <p>24 A. One more time. Figure or page?</p>

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<p style="text-align: right;">Page 86</p> <p>1 Q. Page 5, Figure 4. 2 A. Okay. I am there. 3 Q. Do you see where in Figure 4 there's 4 different staining that was discussed that was done by 5 Dr. Iakovlev? 6 A. (No response.) 7 Q. If you look at -- on Image (a) on Figure 4 -- 8 A. Correct. 9 Q. -- Von Kossa staining -- do you see that -- 10 was negative for calcium in the brittle bark? 11 A. That's what it says, correct. 12 Q. Says, (b), "Trichrome stain shows that the 13 deeper parts of the bark have smaller staining porosity 14 (red) than those close to the surface (green) which 15 correlates with TEM," transmission electron microscopy, 16 "findings." Do you see that? 17 A. Yes, that's what it says under (b), yes. 18 Q. Okay. You didn't use trichrome, right? 19 A. We did not. 20 Q. Okay. And do you have any opinions about why 21 in (b), why trichrome would be able to be trapped 22 within the degraded -- what we allege to be the 23 degraded layer of the PROLENE fibers? 24 MR. THOMAS: Object to form of the question.</p>	<p style="text-align: right;">Page 88</p> <p>1 PROLENE or some other material. It's just talking 2 about the relative size of alleged pores that are on 3 either side of the bark. 4 So to the extent that he uses that technique 5 to determine that it's PROLENE, I would have an 6 opinion. But if he's just using it to talk about 7 porosity and porosity alone, then I wouldn't have an 8 opinion. 9 Q. Would you -- would it be significant to you 10 at all if Dr. Iakovlev conducted additional staining to 11 determine whether or not the outer layer was 12 proteinaceous; used a stain to look for protein, and 13 the outer layer didn't stain? 14 MR. THOMAS: Object to form of the question. 15 Q. Would it be significant, in your opinion, as 16 an expert here, whether or not Dr. Iakovlev had 17 actually done some testing, staining that would 18 identify whether or not that outer layer is protein? 19 MR. THOMAS: Object to form of the question. 20 A. Well, he's already done some of that work 21 today. We know that there's a biological component to 22 this crust layer, because it takes on H&E staining. So 23 I guess I'm missing your point. 24 Q. Well, if you -- well, Dr. Iakovlev's</p>
<p style="text-align: right;">Page 87</p> <p>1 A. I have no opinion on that. 2 Q. You're not going to offer any opinions at 3 the -- at any trial concerning the additional findings 4 of Dr. Iakovlev that are discussed in his publication, 5 in his expert report, and here in Figure 4? 6 MR. THOMAS: Object to form of the question. 7 That's much too broad. 8 A. I don't have any opinions at this time on Von 9 Kossa staining of the crust layer. 10 Q. And you don't have any opinions regarding Von 11 Kossa stainer -- staining of the outer layer of the 12 mesh because you didn't conduct any of those studies. 13 Right? 14 A. I have not conducted any Von Kossa staining 15 studies. 16 Q. Okay. And you don't -- and won't offer any 17 opinions concerning Dr. Iakovlev's trichrome staining 18 and his findings related to the trichrome. 19 MR. THOMAS: Object to form of the question. 20 A. Well, I -- I don't know. I don't know. But 21 at this point in time I can tell you this: That his 22 discussion on the trichrome stain simply talks about 23 porosity that may exist in that crust. It does nothing 24 to characterize that material in terms of whether it's</p>	<p style="text-align: right;">Page 89</p> <p>1 opinion's different than yours, right? Dr. Iakovlev's 2 opinion is that the degraded polypropylene layer traps 3 H&E, which is different than your opinion. We can 4 agree that you have different opinions, right? 5 A. We have -- sure, we can agree on different 6 opinions. 7 Q. Okay. But did you -- would it be important 8 to you if Dr. Iakovlev had done additional protein 9 staining and found that the outer layer did not stain? 10 MR. THOMAS: Object to form of the question. 11 A. I -- I would need to see that research. I'd 12 need to see that study. 13 Q. Well, if you look at Page 5 of his 14 publication, Exhibit 18. 15 A. (Witness complies.) 16 Q. "Immunohistochemical stain for immunoglobulin 17 G (IgG stained brown)." Do you see that? "IgG," 18 immunoglobulin, "is present in almost all human tissues 19 and fluids. It is deposited on the surfaces of 20 degraded polypropylene, but it is not mixed within it." 21 Do you see -- do you see Figure C? 22 A. I do. And I think you're reading the text 23 that corresponds to Figure C. Is that correct? 24 Q. Okay. So do you see Figure C, that when</p>

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<p>1 immunoglobulin staining was conducted, immunoglobulin 2 staining only stains protein brown. Right?</p> <p>3 A. Well, that's what he says, but I haven't done 4 my own research to verify that.</p> <p>5 Q. You don't know one way or the other.</p> <p>6 A. No, but I could certainly find out.</p> <p>7 Q. Okay. But sitting here today, because you're 8 not a pathologist, you don't know one way or the other 9 whether or not immunoglobulin would stain brown in the 10 presence of tissue or fluids.</p> <p>11 A. No. But I know --</p> <p>12 Q. Protein.</p> <p>13 A. No. But I know that H&E stains biological 14 materials. And there's no biological component to 15 native PROLENE.</p> <p>16 Q. Do you understand that immunoglobulin is 17 found within the tissues and the fluids of the human 18 body?</p> <p>19 A. I can only recite what's written here.</p> <p>20 Q. Do you understand that immunoglobulin is 21 found within protein?</p> <p>22 MR. THOMAS: Object to form of the question.</p> <p>23 A. It's the same answer.</p> <p>24 Q. Okay. So do you agree that based on the</p>	<p>1 MR. THOMAS: Object to form of the question. 2 A. If it's -- could you -- I need to hear that 3 question again. 4 (Read back by the reporter.) 5 A. I think it depends on the question I'm going 6 to get asked. Because, like I just mentioned, going 7 back to the trichrome stain, he hasn't used that 8 technique to verify that the cracked layer is PROLENE. 9 So it really is going to come down to what 10 questions I'm asked and -- and how it relates to my 11 polymer science background. That's -- that's how I'll 12 answer that.</p> <p>13 Q. So you're saying that the trichrome staining 14 that was conducted by Dr. Iakovlev doesn't determine 15 whether or not the cracked outer layer is -- is 16 PROLENE?</p> <p>17 A. What I'm saying is the only thing that he's 18 mentioning with respect to trichrome stain is the 19 presence of some alleged set of pores that vary in 20 size. He's not using it as a technique to confirm that 21 the cracked layer is PROLENE or oxidized PROLENE. He's 22 simply making a statement about some, in his opinion, 23 inherent pore size within that layer. We -- he still 24 hasn't identified what that material is within that</p>
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<p>1 staining done, as depicted in Figure (c) of -- 2 Image (c) of Figure 4, it didn't stain brown?</p> <p>3 MR. THOMAS: Object to form of the question. 4 A. (No response.) 5 Q. There is no immunoglobulin within the cracked 6 layer of the PROLENE.</p> <p>7 MR. THOMAS: Object to the form of the 8 question. 9 A. I am -- I am going to leave the 10 interpretation of these figures up to Dr. Iakovlev. 11 These are not my figures, this is not my work. 12 Q. Okay. So you defer to Dr. Iakovlev in 13 that --</p> <p>14 MR. THOMAS: Object to form of the question. 15 A. I'm not -- I'm not deferring to him. I would 16 say he needs to be asked those questions, not me. 17 Q. Okay. You're not going to offer any opinions 18 at trial concerning the images contained within Figure 19 4. 20 A. Not at this time. 21 Q. Okay. And you're not going to be offering 22 any criticisms of Dr. Iakovlev containing -- concerning 23 any of his other opinions as they relate to other 24 histopathological staining that he conducted.</p>	<p>1 layer. 2 In other words, I could have a crust or a 3 cracked layer on the outside of Material X that has 4 nothing to do with PROLENE, and it can still have pores 5 in it. 6 Q. You've seen some of the other work done by 7 Dr. Iakovlev, where he uses polarized light to 8 identify -- to identify polypropylene. Right? 9 MR. THOMAS: Object to form of the question. 10 A. No. He has not. He has identified a 11 material that illuminates. But polarized light by 12 itself does not tell you that the material it's 13 illuminating is PROLENE. 14 Q. Are you going -- 15 A. It just -- it just tells you that you have a 16 material that has some degree of molecular order to it. 17 That's it. 18 Q. Are you going to offer any opinions at trial 19 that tissue or protein -- proteinaceous material is 20 birefringent when reviewed under polarized light 21 microscopy? 22 A. We may. There's certainly evidence of that 23 in some of his micrographs. We see that collagen will 24 actually illuminate to a certain degree under polarized</p>

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<p style="text-align: right;">Page 94</p> <p>1 light.</p> <p>2 Q. Okay. Have you looked at -- have you</p> <p>3 conducted any polarized light experiment to determine</p> <p>4 whether or not protein is birefringent?</p> <p>5 A. (No response.)</p> <p>6 Q. Under polarized light?</p> <p>7 A. (No response.)</p> <p>8 Q. You didn't conduct any separate experiment</p> <p>9 concerning whether or not protein is birefringent,</p> <p>10 right, using polarized light?</p> <p>11 MR. THOMAS: He's looking right now.</p> <p>12 Q. Maybe I can speed things up --</p> <p>13 A. Hold on. I apologize for the delay. It</p> <p>14 depends on the degree of cross-polarization. There are</p> <p>15 certainly some images -- and, again, this will be all</p> <p>16 in the files that you have -- where if you look at</p> <p>17 serum and then some degree of magnification and then</p> <p>18 H&E, which means it's been stained, cross-polarization,</p> <p>19 XPOL, there are certainly several images that are</p> <p>20 viewed under polarized light that show the serum</p> <p>21 proteins; that they're illuminated in those</p> <p>22 micrographs.</p> <p>23 So there is some degree of illumination of a</p> <p>24 proteinaceous material in my vials. I can show you an</p>	<p style="text-align: right;">Page 96</p> <p>1 looking at -- with polarized light?</p> <p>2 A. Correct.</p> <p>3 Q. And that was done by Dr. Benight?</p> <p>4 A. Correct.</p> <p>5 Q. And it's your testimony that the bovine serum</p> <p>6 experiment demonstrated that bovine serum protein is to</p> <p>7 some degree birefringent?</p> <p>8 A. It illuminates under polarized light.</p> <p>9 Q. Okay. And was the -- that was -- in the</p> <p>10 bovine serum experiments, those samples weren't</p> <p>11 oxidized. Right?</p> <p>12 A. Correct.</p> <p>13 Q. If you look at -- if you turn to Figure 18 of</p> <p>14 your report.</p> <p>15 MR. THOMAS: Which one? The supplemental?</p> <p>16 MR. THORNBURGH: The supplemental report.</p> <p>17 MR. THOMAS: Page 27?</p> <p>18 MR. THORNBURGH: Yeah.</p> <p>19 Q. I'm sorry, Page 28, Figure 19. Supplemental</p> <p>20 report, Exhibit 15. You have some images of the</p> <p>21 UV-oxidized or QUV-oxidized PROLENE fibers?</p> <p>22 A. (No response.)</p> <p>23 Q. Are you there?</p> <p>24 A. Yes, I am.</p>
<p style="text-align: right;">Page 95</p> <p>1 image, if that helps.</p> <p>2 Q. You were just reading -- let me see what</p> <p>3 you're looking at.</p> <p>4 A. (Witness indicates.) And the file name is in</p> <p>5 the top left-hand corner, if you want me to read that</p> <p>6 into the record.</p> <p>7 Q. Yes, read -- it's at</p> <p>8 15791_serum_R_63XH&EXPOL_03-imageexport-29? Is that</p> <p>9 the file?</p> <p>10 A. Correct.</p> <p>11 Q. And who took that image?</p> <p>12 A. It would be -- Dr. Benight took this image</p> <p>13 for me.</p> <p>14 Q. And what is that image of?</p> <p>15 A. This is a microtome sample of a mesh that was</p> <p>16 put through the protocols that we've talked about, but</p> <p>17 it includes the presence of bovine serum on the outside</p> <p>18 of the mesh.</p> <p>19 Q. Okay. So you say that that -- the bovine</p> <p>20 serum experiment you conducted went through the same</p> <p>21 protocol as the -- as outlined in the paraffin</p> <p>22 embedding?</p> <p>23 A. Correct.</p> <p>24 Q. And then it was polarized -- or analyzed</p>	<p style="text-align: right;">Page 97</p> <p>1 Q. Okay. And you write that, "Fibers with</p> <p>2 several cracks embedded in paraffin. No staining is</p> <p>3 evident. Mesh fibers are shown under bright field</p> <p>4 light, (a) and (b), and illuminated under</p> <p>5 cross-polarized light, (c)."</p> <p>6 And the cracking that you describe here in</p> <p>7 these figures -- let me ask you this question: Do you</p> <p>8 know what "chatter" is?</p> <p>9 A. In a general sense I know what chatter is.</p> <p>10 Maybe -- maybe you can help me define it.</p> <p>11 Q. In the pathology field, field of pathology</p> <p>12 and microtoming, do you know what "chatter" is?</p> <p>13 A. I don't know if I've heard it expressed as</p> <p>14 the term "chatter", but perhaps you're talking about</p> <p>15 the blade chattering as it comes across the</p> <p>16 cross-section? Am I correct? Is that what you're --</p> <p>17 Q. Right.</p> <p>18 A. -- describing?</p> <p>19 Q. Right. So you -- when the microtome blade</p> <p>20 isn't sharp enough, it can create chatter, right,</p> <p>21 where it comes across the fiber during the</p> <p>22 cross-section and cracks it -- the material up.</p> <p>23 A. I understand what you mean by "chatter". I'm</p> <p>24 not going to agree with the whole notion that it</p>

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<p>1 necessarily cracks things up. But go ahead and ask 2 your question.</p> <p>3 Q. Okay. What do -- well, I need to know what 4 your basis is for -- so let me just -- if you look at 5 Figure 19, (b) and (c), you describe this as cracks 6 caused by the UV oxidation.</p> <p>7 A. You bet.</p> <p>8 Q. Okay. And have you ever seen chatter under a 9 microscope?</p> <p>10 A. I've certainly seen on occasion some 11 artifacts on a microtome surface that might be related 12 to the movement of the blade.</p> <p>13 Q. Has anybody ever trained you on how to 14 identify artifact caused by chatter?</p> <p>15 A. I don't know if anyone has formally trained 16 me, but I've been doing microtoming for 20 years, and I 17 understand the general phenomenon that you're 18 describing.</p> <p>19 Q. And in Figure (d) and (c), you don't believe 20 those -- that cracking that's demonstrated on these 21 images is actually chatter, rather than cracks caused 22 by the oxidation of PROLENE?</p> <p>23 A. Here's what I can tell you: These samples 24 are definitively cracked, because if you look at the</p>	<p>1 Q. In Figure 19 (b) and (d), are those images of 2 the mesh fibers or the suture fiber?</p> <p>3 A. Those are mesh fibers. And I'm just going to 4 correct the record. That's (b) as in boy, (c) as in 5 Charlie.</p> <p>6 Q. Correct. Did you identify -- strike that.</p> <p>7 Who took the images, the microscopy images?</p> <p>8 A. Dr. Benight, with some assistance from 9 Dr. Garcia.</p> <p>10 Q. Okay. And prior to her involvement in this 11 litigation, had she ever taken -- had she -- strike 12 that.</p> <p>13 Prior to her involvement in this litigation, 14 had she ever done microscopy imaging before?</p> <p>15 A. I'm sure she has, but I have to -- I would 16 either defer to her CV or whatever she's testified to.</p> <p>17 Q. Do you know whether or not she's ever done 18 microscopy before?</p> <p>19 MR. THOMAS: Microscopy or --</p> <p>20 Q. Microscopy imaging.</p> <p>21 A. I can certainly look it up. She might 22 reference it on her CV.</p> <p>23 Q. I only say this because I -- you know, when I 24 looked at the materials that were produced yesterday,</p>
<p style="text-align: center;">Page 99</p> <p>1 pre-microtomed micrographs, all of these specimens are 2 riddled with cracks.</p> <p>3 And, more importantly, when we went from the 4 whole fiber specimen down to the microtoming, we 5 actually denoted where we were going to do the 6 microtoming so that our microtomes would align with 7 known cracks from the oxidation process.</p> <p>8 So there's zero doubt in my mind that cracks 9 that are shown on these images are a result of 10 UV oxidation.</p> <p>11 And -- and just let me add to that. We've 12 done the FTIR work to confirm oxidation was achieved.</p> <p>13 Q. The cracking that you observed in the 14 UV-treated specimens, did that cracking penetrate 15 through the entire fiber, or did it only go to a 16 certain depth?</p> <p>17 A. It depends. I think for some of the PROLENE 18 fibers -- sutures, rather, we got some pretty 19 significant cracking and damage throughout -- I'll call 20 it the bulk of the suture.</p> <p>21 In the mesh, I would say more of it was 22 around the perimeter, like we've seen before. Similar 23 to what we saw in the microstaining -- in the 24 microscopy work last fall.</p>	<p style="text-align: center;">Page 101</p> <p>1 the microscopy images and the microscopy that was 2 produced in the Mullins case, those images were very 3 blurry.</p> <p>4 MR. THOMAS: Which ones?</p> <p>5 MR. THORNBURGH: Virtually all of them.</p> <p>6 Q. I mean, you've seen them, right?</p> <p>7 A. I have seen them.</p> <p>8 Q. They're pretty poor images. Right?</p> <p>9 A. I would -- I would argue that it was still 10 clear enough to discern what was stained and not 11 stained. But we certainly attempted to improve on our 12 microscopy this time around, in terms of their visual 13 clarity.</p> <p>14 Q. Okay. The visual clarity, even this time 15 around, wasn't very good, were they?</p> <p>16 MR. THOMAS: Object to form.</p> <p>17 A. No, I disagree. They're fine. I think that 18 they're very good.</p> <p>19 Q. Well, turn to Page 25.</p> <p>20 A. (Witness complies.) Okay.</p> <p>21 Q. I'm just going to use this as an example. 25 22 of your report, there's a Figure 15. Blurry image, 23 right?</p> <p>24 A. Only a portion that's in a different focal</p>

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<p style="text-align: right;">Page 102</p> <p>1 plane is blurry.</p> <p>2 Q. There's a -- the focal point in the right and</p> <p>3 left of this image is blurry.</p> <p>4 MR. THOMAS: Object to form.</p> <p>5 A. There is some discreet regions that are</p> <p>6 blurry, but it's -- it's not because of the microscope,</p> <p>7 it's not because of the user. It's because of the</p> <p>8 focal plane that you're focusing in on.</p> <p>9 Not -- like we talked about six months ago,</p> <p>10 not all these specimens are perfectly flat. There's</p> <p>11 going to be some slight variability. And you're at the</p> <p>12 micron level. So when you're zoomed in this close on a</p> <p>13 specimen that's not ideally flat, you're going to be in</p> <p>14 different focal planes. It's inevitable.</p> <p>15 Q. If you look at (b), it's also blurry.</p> <p>16 MR. THOMAS: Object to form.</p> <p>17 A. I'm sorry; which one?</p> <p>18 Q. Figure 15, Image (b) is blurry.</p> <p>19 MR. THOMAS: Object to form.</p> <p>20 A. No. Not -- no. Not every region is blurry.</p> <p>21 There are certainly some areas -- there are certainly</p> <p>22 some areas that are not blurry.</p> <p>23 Q. Turn to 26.</p> <p>24 A. (Witness complies.) All three of these</p>	<p style="text-align: right;">Page 104</p> <p>1 Q. Can you point out for me on any of these</p> <p>2 images where the degraded -- on these microphotographs,</p> <p>3 where the degraded outer layer of the PROLENE fiber</p> <p>4 begins and ends?</p> <p>5 MR. THOMAS: On which images are you talking</p> <p>6 about?</p> <p>7 A. Yeah, which images?</p> <p>8 Q. On any image in your report.</p> <p>9 A. Well, for the -- for the chemically oxidized,</p> <p>10 it would be all of the exterior surfaces, because</p> <p>11 they've all seen the same chemical environment.</p> <p>12 So when we confirmed through our spectroscopy</p> <p>13 that oxidation was achieved, it would be all of the</p> <p>14 surfaces. It wouldn't be just in the discreet regions.</p> <p>15 That -- I'm giving you that answer because</p> <p>16 we -- the last thing we were on was on Page 26.</p> <p>17 Q. I'm just trying to understand this. In the</p> <p>18 images I look at, I don't see the degraded outer layer.</p> <p>19 A. Be more specific. In what?</p> <p>20 Q. I don't see a degraded, cracked outer layer</p> <p>21 on any of these microphotographs that you've provided.</p> <p>22 MR. THOMAS: Anywhere in the report?</p> <p>23 A. Did you look at the SEM images? They're --</p> <p>24 they're riddled with cracks.</p>
<p style="text-align: right;">Page 103</p> <p>1 images are blurred out.</p> <p>2 MR. THOMAS: Object to form.</p> <p>3 Q. Right?</p> <p>4 A. I disagree. There are certainly discreet</p> <p>5 regions that are in focus, and that's what we would</p> <p>6 expect.</p> <p>7 Q. Do you -- you see on Page 26, the bottom</p> <p>8 image, is there any area on that image that isn't</p> <p>9 blurry?</p> <p>10 A. I'm going to look at the native image,</p> <p>11 because I don't think that's a fair indication of</p> <p>12 what's blurry and what's not blurry with that size</p> <p>13 micrograph inside to record it.</p> <p>14 Q. While you're looking at it, did you ever go</p> <p>15 back and talk to Miss Benight and ask her if she could</p> <p>16 take some better images?</p> <p>17 A. No. I was happy with the images that she</p> <p>18 made.</p> <p>19 Q. You were happy with the images that Dr.</p> <p>20 Benight provided to you?</p> <p>21 A. Yeah. Not every -- at this magnification,</p> <p>22 this sample size, not every single one of them is going</p> <p>23 to be a perfect picture, if you will. It's just not --</p> <p>24 it's just not realistic.</p>	<p style="text-align: right;">Page 105</p> <p>1 Q. Well, but the SEM images are a different</p> <p>2 image. Right?</p> <p>3 A. No. What I'm explaining to you is when the</p> <p>4 SEM -- when the individual fibers were cracked, we</p> <p>5 mounted those specimens on a mounting board, and we</p> <p>6 actually noted, look, here's a specific crack, let's</p> <p>7 microtome right through this cracked region. So, in</p> <p>8 essence, this one-to-one correlation between SEM</p> <p>9 cracking and the cracks that are -- the cracking that's</p> <p>10 exhibited around some of the QUV specimens that we</p> <p>11 talked about.</p> <p>12 Q. You'd expect that if you took a -- what you</p> <p>13 called an intentionally oxidized PROLENE sample --</p> <p>14 A. Which method?</p> <p>15 Q. Using QUV.</p> <p>16 A. Okay.</p> <p>17 Q. -- and you looked at it under the standing</p> <p>18 electron microscopy, and you saw the severe cracking</p> <p>19 that some of your images have demonstrated --</p> <p>20 A. Correct.</p> <p>21 Q. -- then you'd take that same material, and</p> <p>22 you do, you know, embedding and microtoming and do a</p> <p>23 cross-section --</p> <p>24 A. And I --</p>

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<p style="text-align: right;">Page 106</p> <p>1 Q. -- and put it under a microscope -- 2 A. Sure. 3 Q. -- you expect to see that outer degraded 4 layer in the microphotograph. Right? 5 A. Yeah, and we -- and we do. It's on 6 -- it's 6 on 19 (b). I mean, the cracking that's at -- if I use 7 that mesh cross-section as a clock, you know, certainly 8 the cracking that we see at 9:00, 10:00, 11:00, I am a 9 hundred percent convinced that that is from UV 10 oxidation. 11 Q. You think that's from UV oxidation and not 12 chatter. 13 A. I do. 14 Q. Okay. 15 A. Again, that's for two reasons. One, we've 16 confirmed it through FTIR. That's -- there's certainty 17 there. And then, two, we've got it connected back to 18 the SEM microcracks. 19 Q. So how do I connect Figure (b) and (c) -- 20 which are the same image, right? Same fiber, right? 21 A. Yes. 22 Q. How do I track backwards this figure to a 23 scanning electron microscopy and then to FTIR? 24 A. It's all in the files that we've given you.</p>	<p style="text-align: right;">Page 108</p> <p>1 A. Okay. It doesn't look like chatter to me. 2 And -- and the chatter -- we know it's not chatter 3 because of the reasons that I just walked you through. 4 Q. Is this sample -- has this sample been 5 preserved? 6 A. Sure. Yes. 7 Q. And where is it being preserved at? 8 A. In Menlo Park. 9 Q. Are all the samples preserved at -- where did 10 you say? 11 A. Menlo Park. That's our -- that's where 12 Dr. Benight and Dr. Garcia work from. 13 Q. Menlo Park is -- 14 A. That's two words; Menlo Park in California. 15 Q. California. 16 A. (Witness nods head.) 17 Q. Did you look at any of these images yourself 18 under a microscope? 19 A. We may have done some video sharing at some 20 point to get some realtime microscopy across the 21 country. I've also looked at all of the ones from the 22 Mullins work first-hand. 23 Q. You have some additional -- so the only ones 24 that you looked at first-hand were for Mullins. You</p>
<p style="text-align: right;">Page 107</p> <p>1 All of -- all of that one-to-one correspondence exists. 2 If you can -- if and when you can find these images on 3 the information we've given you, you find that image, 4 and you trace it back to the overall bulk swath 5 specimens that we've talked about, you will see how 6 they are mounted, you will see the location that we 7 chose to microtome from. It's all there. 8 Q. This image on Figure 19, is this the best 9 image that you had of an intentionally oxidized 10 PROLENE sample? 11 MR. THOMAS: Object to form. 12 Q. For microphotograph -- 13 A. I don't know -- 14 Q. -- imaging? 15 A. I don't know if it's the best. It's 16 certainly a representative fiber that suffered from UV 17 oxidation. 18 Q. And the image is blurry, right? 19 A. No. I don't think the image is blurry. 20 Q. You don't think the image is blurry? 21 A. No. Can you not see the cracking at 9:00, 22 10:00, 11:00? Can you not see that? Because I -- 23 Q. I see some cracking, but it looks like -- 24 that looks like chatter to me.</p>	<p style="text-align: right;">Page 109</p> <p>1 didn't look at any of these -- 2 MR. THOMAS: Object to form. 3 A. I've looked at all of those. 4 Q. Through the microphotographed images that 5 were sent to you from Dr. Benight. 6 A. Yeah. And/or a -- some sort of video session 7 that we might have set up at some point in time. 8 Q. On Page 30 -- or, actually, Page 31, you talk 9 about polarizing artifact. 10 A. Yes. 11 Q. And here you are -- I think what you're doing 12 is you're attempting to demonstrate what you believe 13 the -- it's your opinion that the cracked outer layer 14 that is identified by Dr. Iakovlev is artifact from 15 polarized light microscopy? 16 A. Oh, no. Not necessarily. It's -- this is 17 just a caution and a warning that when you use 18 polarized lighting, that you can get some degree of 19 shading and some -- and varying degrees of 20 illumination, and you just need to be aware of those 21 artifacts as you interpret the results. 22 Q. Are you going to offer any opinion at trial 23 that any of the photo -- or the microphotographs that 24 you've looked at that were taken by Dr. Iakovlev were</p>

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<p style="text-align: right;">Page 110</p> <p>1 caused by polarizing artifact? 2 A. I don't know. I'd have to go back and look 3 at his universe of images. All I'm saying here is that 4 when you use polarized light, you just need to be 5 careful, because you could introduce things that just 6 truly aren't there. That's -- that's all I'm saying. 7 MR. THOMAS: And just so you know, just in 8 case you don't know, there are two videos in 9 the information -- 10 MR. THORNBURGH: I've seen those. 11 MR. THOMAS: Okay. 12 MR. THORNBURGH: I've seen those. 13 MR. THOMAS: That's fine. 14 Q. Are you offering -- are you -- have -- 15 sitting here right now, do you have any opinion that 16 any of the microphotographs that were taken from -- by 17 Dr. Iakovlev and are in his expert report are actually 18 depicting some sort of polarizing artifact? 19 MR. THOMAS: Object to form. 20 A. I can say this: That there may be polarizing 21 artifacts in his images. If you're asking me if I 22 believe that the crust that we've all been talking 23 about for a very long time is an artifact of polarized 24 light, the answer's no.</p>	<p style="text-align: right;">Page 112</p> <p>1 I'm in specifically Image (c) as in Charlie. 2 Q. Okay. 3 A. Are you with me? 4 Q. Yeah, I'm there. 5 A. So in that particular image, I clearly see a 6 stained region that's just in -- I'll call it inboard 7 from the white reference arrow, and then a defined 8 boundary between -- there's no staining in the blue 9 particles. 10 So, to me, this is a clear indication that 11 the crust is something else, for two reasons: There's 12 no blue granules in the purple swath of material that 13 you see there, is a discreet boundary, and, likewise, 14 there's no staining in and around the blue dyes, the 15 blue particles. 16 So I -- I see it very differently than he 17 does. 18 Q. So let me ask you this question: Do you 19 know -- do you have any understanding as to whether or 20 not those blue granules will also oxidize and degrade 21 over time? 22 A. The blue granules -- 23 Q. Um-hum. 24 A. -- themselves?</p>
<p style="text-align: right;">Page 111</p> <p>1 Q. Okay. And you've seen that in the 2 degraded -- what we call the degraded crust or degraded 3 bark, that Dr. Iakovlev has found that within that 4 cracked layer, there are blue granules caused from the 5 placement of those dye or the pigments during the 6 manufacturing by the Defendant. Right? 7 A. I -- 8 Q. So, in other words, the Defendant uses a -- 9 blue granules or blue pigments to -- to color their 10 fibers blue. Right? 11 A. Correct. 12 Q. And in the cracked outer layer of the mesh 13 that Dr. Iakovlev has looked at, in that cracked layer, 14 there are blue pigments or blue granules. Okay? 15 MR. THOMAS: Object to the form of the 16 question. 17 A. I think that is his interpretation of what he 18 sees. 19 Q. What is your interpretation of what is shown 20 in the microphotographs of Dr. Iakovlev? 21 A. I think I -- I see two discreet layers, and I 22 can show you an image that will help tease that out. 23 So if you look at Dr. Iakovlev's Wave 1 24 report, Page 94. I'm in Figure 13(k), as in Karen, and</p>	<p style="text-align: right;">Page 113</p> <p>1 Q. Right. 2 A. I haven't thought about that enough. I would 3 have to think about that before I give you an answer. 4 Q. Okay. Because if they did, it would make 5 sense that towards the surface, where the highest 6 activity of oxidation is occurring of the fibers, that 7 you'd expect to see a decrease in the blue fibers at 8 that level. 9 A. Well, fine. Let's continue that logic, then. 10 What is the answer as to why the inner boundary didn't 11 stain? 12 Q. Where are you looking at? 13 A. I'm just looking to the left -- let me just 14 point it out to you so we're all on the same page. 15 Q. Well, let me just -- let's just do this real 16 quick. 17 A. Sure. 18 Q. We're running out of time. 19 A. Okay. 20 Q. Let's look at Exhibit No. -- or Image No. (d) 21 of Figure -- of this figure set. Okay? On Page 94. 22 Do you see (d)? 23 A. I see (d). 24 Q. Okay. Do you see the detached degraded --</p>

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<p>1 what we have allege to be degraded bark?</p> <p>2 A. I do.</p> <p>3 MR. THOMAS: Object to form of the question.</p> <p>4 Q. Do you see the blue granules throughout that</p> <p>5 degraded layer?</p> <p>6 A. I do.</p> <p>7 MR. THOMAS: Object to form.</p> <p>8 Q. Okay. And what is your explanation for the</p> <p>9 degradation and the presence of the blue granules in</p> <p>10 this image?</p> <p>11 A. Well, because what you can have on a</p> <p>12 biased-cut specimen, you can actually have two layers</p> <p>13 of material. And you're only looking at a</p> <p>14 one-dimensional image here.</p> <p>15 So if this has, say, a portion -- and I</p> <p>16 talked about this in one of my reports. Because of the</p> <p>17 bias cutting, I can have the crust layer on top, if you</p> <p>18 will, and then some of the residual PROLENE on the</p> <p>19 bottom of that same specimen. And so when I look at it</p> <p>20 top down, I'm actually looking through both</p> <p>21 simultaneously.</p> <p>22 Q. So what evidence do you have that you're</p> <p>23 looking at a crust layer that is on top of a</p> <p>24 polypropylene layer causing this image to look the way</p>	<p>1 across some sort of arbitrary plane, I'm also going to</p> <p>2 have some degree of bias cutting.</p> <p>3 And what I'm saying is that, yes, if I have a</p> <p>4 bias cut and now I place it on a slide, I may have the</p> <p>5 notion of two materials, one which is PROLENE, and one</p> <p>6 which is the crust in the same field of view looking</p> <p>7 top down.</p> <p>8 Q. There's no evidence in -- on Page 94 of</p> <p>9 Dr. Iakovlev's report, Image (d), of a bias view or</p> <p>10 bias cut.</p> <p>11 A. We can't tell here. You need to actually</p> <p>12 look at the entire cross-section farther away to know</p> <p>13 whether you've got a perfect circle or some sort of</p> <p>14 bias. You just can't tell.</p> <p>15 Q. Because I think the way you've described it</p> <p>16 is that if you have a biased cut, where it's not a</p> <p>17 totally flat cross-section, then at -- then the crust</p> <p>18 could look as if it has blue granules in it, but it's</p> <p>19 really an artifact caused by the core.</p> <p>20 A. Not necessarily the core. It could be any</p> <p>21 residual PROLENE that's sitting just below the crust</p> <p>22 itself. So it doesn't have to be the core. I know why</p> <p>23 you're asking that, because (d) has no core in it. You</p> <p>24 don't have to have the core.</p>
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<p>1 it does?</p> <p>2 A. You can actually just show it through basic</p> <p>3 geometry. If you cut a basic -- excuse me. If you</p> <p>4 have a bias-cut fiber, you can actually just show it</p> <p>5 through simple geometry, that you can have this -- what</p> <p>6 I'll call a compounding effect; one material on top of</p> <p>7 the other around the perimeter.</p> <p>8 Q. Is that what you were attempting to do in</p> <p>9 your supplemental report on Page 31?</p> <p>10 A. No. No. 31 was just talking about artifacts</p> <p>11 that come up from the -- that come about from the</p> <p>12 polarization process or the polarized light</p> <p>13 illumination.</p> <p>14 Q. On Page 30? Is that what you're referring</p> <p>15 to?</p> <p>16 A. Yeah, to some extent. I mean, this is just</p> <p>17 showing how you can have this bias cut that we talked</p> <p>18 about.</p> <p>19 So if you look at Image (b) -- Figure 21,</p> <p>20 Image (b), you can -- none of these specimen, when you</p> <p>21 microtome them, you don't -- you aren't guaranteed a</p> <p>22 perfect circle. Is that clear? Does that make sense?</p> <p>23 Because of the fact that the mesh is a</p> <p>24 three-dimensional knit. And so when I microtome up</p>	<p>1 It's just a matter of that -- that banded</p> <p>2 crust material coming from a bias cut could -- could be</p> <p>3 two different materials, one on top of the other. And</p> <p>4 you're making -- you're getting an illusion of the blue</p> <p>5 dyes and the blue granules being inside of the crust.</p> <p>6 Q. So you think -- it's your opinion, on Page</p> <p>7 94, that Image (d) is actually an illusion.</p> <p>8 A. I'd need to see that -- I'd need to see that</p> <p>9 specimen first-hand to be able to make that assessment.</p> <p>10 Q. So you can't offer an opinion to a reasonable</p> <p>11 degree of scientific probability or certainty that the</p> <p>12 image on Page 94, (d), is caused by an artifact.</p> <p>13 A. There's no question I can demonstrate that</p> <p>14 through simple geometry. You know, it's just an</p> <p>15 extension of what's on Figure 21.</p> <p>16 I can show that you can get a multi-layer</p> <p>17 optical illusion, if you will, by having a bias-cut</p> <p>18 specimen. There's no doubt.</p> <p>19 Q. Have you attempted to reproduce this artifact</p> <p>20 in any of your images?</p> <p>21 MR. THOMAS: Object to form of the question.</p> <p>22 A. Yes. So in the bovine serum specimens, we</p> <p>23 definitely have some micrographs that show when you</p> <p>24 have an overlap of a proteinaceous material on top of</p>

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<p style="text-align: right;">Page 118</p> <p>1 the outside perimeter of the fiber, that you can have 2 the illusion of blue granules in some sort of protein 3 crust.</p> <p>4 Q. What image are you referring to in your 5 report?</p> <p>6 A. I'm trying to find it right now. I can 7 rattle off the file name when you're ready.</p> <p>8 Q. Ready.</p> <p>9 A. Okay. 157183_serum_R -- as in Robert -- 10 _63X_H&E_ANA --</p> <p>11 (Discussion held off the record.)</p> <p>12 A. -- _06-imageexport40. And then I'm not going 13 to make you go through that whole thing again, but the 14 next one is --</p> <p>15 (Discussion held off the record.)</p> <p>16 A. -- imageexport16.</p> <p>17 Q. And that's not in your expert report. That's 18 just a microphotograph?</p> <p>19 MR. THOMAS: Object to the form of the 20 question.</p> <p>21 A. It would certainly be in the -- it is, 22 actually. One of them is. So Figure 14 (b), as in 23 boy, would be one of them. And, likewise, Figure 15 24 (a) and (b) show overlapping of the bovine serum -- the</p>	<p style="text-align: right;">Page 120</p> <p>1 oxidation.</p> <p>2 A. There was some oxidation species, correct.</p> <p>3 Q. Okay. So you were actually able to begin the 4 oxidation process using the chemicals in your protocol.</p> <p>5 A. Yes. We found some evidence of oxidation.</p> <p>6 Q. And were you trying to mimic the in vivo 7 environment where these meshes are placed in a woman's 8 body?</p> <p>9 MR. THOMAS: Object to the form of the 10 question.</p> <p>11 A. No, not at all.</p> <p>12 Q. Did any of your experiments mimic the in vivo 13 environment of a woman's body?</p> <p>14 A. No.</p> <p>15 Q. If you look at your protocol, you actually 16 added a step to -- to Dr. Guelcher's protocol, didn't 17 you?</p> <p>18 A. Can you just orient me so we can save time.</p> <p>19 Q. Okay. Let's go ahead and mark as exhibit --</p> <p>20 mark as an exhibit the Guelcher Chemical Oxidation 21 Protocol.</p> <p>22 (MacLean Deposition Exhibit 19 - Guelcher 23 Chemical Oxidation Protocol - marked for 24 identification.)</p>
<p style="text-align: right;">Page 119</p> <p>1 fixed bovine serum with the mesh specimen.</p> <p>2 Q. Doctor, if you turn to -- let's look at your 3 protocol for the chemical oxidizing experiment that you 4 did.</p> <p>5 A. Okay. (Witness complies.)</p> <p>6 Q. Okay. Do you have it in front of you?</p> <p>7 A. I do. I just want to make sure we're working 8 off the same document. So mine says "Guelcher Chemical 9 Oxidation Protocol".</p> <p>10 Q. Right. And, again, was it your -- the 11 purpose of following Dr. Guelcher's protocol was to see 12 if -- was, again, I guess, to use it as a control?</p> <p>13 A. We were -- we wanted to actually include a 14 chemical oxidation technique in addition to the QUV 15 technique.</p> <p>16 Q. Okay. And so you were attempting to see if 17 you could produce the results of Dr. Guelcher.</p> <p>18 MR. THOMAS: Object to form of the question.</p> <p>19 A. No, not necessarily. We were using it as a 20 method, an established method in the literature for 21 oxidizing polypropylene-based materials. That's all.</p> <p>22 Chemically oxidizing polypropylene-based material.</p> <p>23 Q. And you actually did find evidence in your 24 FTIR analysis of the chemically oxidized samples of</p>	<p style="text-align: right;">Page 121</p> <p>1 MR. THOMAS: Do you have an extra one, Dan? 2 What number did we mark that?</p> <p>3 THE WITNESS: It was 19.</p> <p>4 MR. THORNBURGH: 19.</p> <p>5 Q. In your protocol, you used ultrasonic 6 cleaning, right?</p> <p>7 A. Can you just -- again, just for sake of time, 8 just orient me to what number or what page you're on.</p> <p>9 Q. Okay. So if we're on Exhibit 19, do you see 10 the top, you talk about the equipment and supplies. 11 Then you talk about the procedure.</p> <p>12 A. Yes.</p> <p>13 Q. At the bottom of Page 1.</p> <p>14 A. (Witness nods head.)</p> <p>15 Q. And then you talk about on Page 2 the 16 chemical oxidation protocol.</p> <p>17 A. Yes.</p> <p>18 Q. And you go through the protocol, and you 19 discuss on Section 6, sonicating, if necessary, to 20 remove any cobalt chloride crystals.</p> <p>21 A. Yes. Correct.</p> <p>22 Q. Did you sonicate any of the chemical 23 oxidation samples or the chemically treated samples?</p> <p>24 A. I believe so. We did. We tried to remove</p>

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<p>1 some of the cobalt crystals that were adhered to some 2 of the fibers.</p> <p>3 Q. Okay. And you did that in an ultrasonic bath 4 or --</p> <p>5 A. We did.</p> <p>6 Q. Okay. And what type of cleaning solution did 7 you use?</p> <p>8 A. I believe it was just distilled water.</p> <p>9 Q. So you put the samples into the ultrasonic 10 bath with distilled water?</p> <p>11 A. Correct.</p> <p>12 Q. No other ultrasonic fluid was used?</p> <p>13 A. No.</p> <p>14 Q. You'd agree that that's a different protocol 15 than was used by Dr. Guelcher?</p> <p>16 A. I don't recall. I don't have them side by 17 side. But it would -- it doesn't affect the results.</p> <p>18 You're just trying to remove these crystals that are 19 now sitting on the surface. There's no interaction 20 between them.</p> <p>21 Q. Well, why did you add this step if it wasn't 22 part of Dr. Dunn and Guelcher's protocol?</p> <p>23 A. Because we wanted to isolate the fibers, and 24 we had so many of the cobalt crystal -- crystals --</p>	<p>1 1.</p> <p>2 A. And what page is that on?</p> <p>3 Q. It's actually your supplemental report, 4 Page 11.</p> <p>5 A. (Witness complies.) Okay.</p> <p>6 Q. This Table 1 discusses the PROLENE samples 7 that were processed --</p> <p>8 A. Correct.</p> <p>9 Q. -- in your experiment.</p> <p>10 A. Correct.</p> <p>11 Q. And you expose -- we talked about all the 12 samples that were exposed to QUV resin. But if you 13 look at Column -- let's see here. Actually, strike 14 that.</p> <p>15 Let's just turn real quick to Page 176 of 16 your supplemental report.</p> <p>17 A. (Witness complies.) 176.</p> <p>18 Q. Is this where your FTIR analysis begins on -- 19 in the experiments that you conducted?</p> <p>20 A. Correct.</p> <p>21 Q. Okay. And on Page 176, you have a number of 22 controls?</p> <p>23 A. I do.</p> <p>24 Q. And then on Page 177, you have additional</p>
<p style="text-align: center;">Page 123</p> <p>1 excuse me -- cobalt chloride crystals that were 2 adhering to the surface that we wanted to remove them. 3 That's all.</p> <p>4 Q. Did you use ultrasonic cleaning in any of the 5 UV-treated samples?</p> <p>6 A. We did not.</p> <p>7 Q. Okay. And have you read any publications 8 that discuss how using -- or how the abrasive steps are 9 taken in cleaning explanted samples can actually remove 10 the degraded surface layer?</p> <p>11 MR. THOMAS: Object to form of the question.</p> <p>12 A. I know that when some people have cleaned 13 explanted specimens, that there is a removal of this 14 crust, if that's what you're asking me.</p> <p>15 Q. Did you, in any of your experiments that you 16 conducted -- were you ever asked to see whether or not 17 the cleaning steps that are used by, for example, 18 Dr. Timms (phonetic) can actually remove the oxidized 19 degraded surface layer?</p> <p>20 A. That's a question for Dr. Timms. I didn't do 21 that work.</p> <p>22 Q. You weren't asked to do that work?</p> <p>23 A. I was not.</p> <p>24 Q. Turn to Table 1 of your expert report in Wave</p>	<p style="text-align: center;">Page 125</p> <p>1 controls. And then you get, finally, to Page 180, it 2 looks like; the FTIR related to the QUV experiment.</p> <p>3 A. Yes.</p> <p>4 Q. And these are samples that are actually 5 treated with QUV, right?</p> <p>6 A. Correct.</p> <p>7 MR. THOMAS: It's 11:45.</p> <p>8 (Discussion held off the record.)</p> <p>9 Q. If you look at the images on Page 180, the 10 FTIR, you have identified some carbonyls that are 11 consistent with degradation, right?</p> <p>12 MR. THOMAS: Object to form.</p> <p>13 Q. And oxidation.</p> <p>14 MR. THOMAS: Object to form of the question.</p> <p>15 A. I will say that there are carbonyls where I 16 would expect them to be between 16- and 1800.</p> <p>17 Q. Where you would expect them to be in a 18 oxidized material, polypropylene material, right?</p> <p>19 A. Correct. That would be one -- that would be 20 one indication or that would be one reason why 21 carbonyls would form in that area.</p> <p>22 Q. Okay. And it's a broad band -- I think you 23 said a broad band, between 1600 -- 1650 and 1800?</p> <p>24 A. Yeah. More or less.</p>

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<p style="text-align: right;">Page 126</p> <p>1 Q. Okay. And that would be -- it's your 2 opinion, as a polymer scientist, that a carbonyl within 3 that location would be consistent with oxidized 4 polypropylene.</p> <p>5 MR. THOMAS: Object to the form of the 6 question.</p> <p>7 A. Let's be clear about this. It's because I 8 know the environment that those specimens were put 9 into. So I can't just look at this spectrum in 10 isolation and say I achieved oxidation.</p> <p>11 It's because I know it went under QUV, I know 12 it started in the pristine state. And once I have 13 those additional factors known to me, and there's no 14 other variables, then, yes, I can ascribe that to 15 oxidation.</p> <p>16 Q. On your chemical-treated samples -- 17 A. Um-hum.</p> <p>18 Q. -- where is the FTIR in your report? 19 A. I don't see it, so it's probably on the thumb 20 drive.</p> <p>21 Q. Why didn't you include the FTIR in your 22 report from the chemically treated samples? 23 A. No reason. Could have just been an 24 oversight. It's definitely in our produced data set.</p>	<p style="text-align: right;">Page 128</p> <p>1 talked about; anywhere from, say, 1650 to 1800. 2 Q. Okay. And how is it different, the 3 QUV-treated, how is that different than the 4 chemical-treated?</p> <p>5 MR. THOMAS: Object to form of the question. 6 A. One is oxidized through chemicals, one is 7 oxidized through UV radiation.</p> <p>8 Q. So the mechanism of action is different? 9 A. I would say the energy imparted to induce 10 oxidation is different. The energy method.</p> <p>11 Q. And I think you said this earlier, but the 12 QUV-treated samples that you -- experiment that you 13 performed, that doesn't happen in the human body.</p> <p>14 A. Well, with the exception of the eye, if we're 15 just talking about pelvic meshes, you're correct.</p> <p>16 Q. So the experiments that you conducted in this 17 case -- I think you testified to this -- did not mimic 18 the environment of the human body.</p> <p>19 A. Correct. And we didn't attempt to do that.</p> <p>20 MR. THORNBURGH: Okay.</p> <p>21 MR. THOMAS: Finished?</p> <p>22 MR. THORNBURGH: Yes. (Discussion held off the record.)</p>
<p style="text-align: right;">Page 127</p> <p>1 Q. Was the FTIR findings of the chemical -- 2 chemically treated samples consistent with the FTIR 3 band seen in the QUV-treated samples? 4 A. I wouldn't -- 5 MR. THOMAS: Object to the form of the 6 question. 7 A. I wouldn't use the word "consistent" or 8 "inconsistent". There were, I would say, different 9 oxidation species that developed under chemical 10 oxidation.</p> <p>11 Q. Okay. Which oxidation species developed 12 under chemical oxidation? 13 A. We saw hydroxyl formation in the 32- to 3500 14 range, and we saw C single bond O in some -- I think in 15 most, if not all, of the specimens at 1050 and 1150.</p> <p>16 MR. THOMAS: I have to stop you, Dan, because 17 I have to ask a few questions, and I have to 18 go. You've been three hours. 19 (Discussion held off the record.)</p> <p>20 BY MR. THORNBURGH: 21 Q. Where were the carbonyl peaks in the 22 chemically treated samples? Where were they located on 23 the spectrum? 24 A. Well, carbonyl peaks would show up like we</p>	<p style="text-align: right;">Page 129</p> <p>1 EXAMINATION 2 BY MR. THOMAS: 3 4 Q. Doctor, I just have a couple questions for 5 you. 6 If you turn to Exhibit No. 14, which is your 7 Wave 1 report, on Pages 36 and 37 there is discussion 8 of papers by Bracco and Imel. 9 A. Correct. 10 Q. Is that correct? 11 A. That is correct. 12 Q. Are those additions to this report? 13 A. They are. I missed those in my first 14 pass-through. I missed Bracco and Imel; would be 15 additions. 16 Q. Those are the only additions beyond what you 17 described to Mr. Thornburgh before? 18 A. That is correct. 19 (MacLean Deposition Exhibit 20 - Publication 20 by Benight, MacLean, Garcia, and Moll - 21 marked for identification.) 22 Q. I want to hand you now what I've marked as 23 MacLean Exhibit No. 20, a document that's contained in 24 what we've produced to Plaintiffs on the thumb drive.</p>

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<p>1 What is Exhibit No. 20?</p> <p>2 A. It is a pending publication regarding the</p> <p>3 work that we did last fall.</p> <p>4 Q. And when you say the "work that you did last</p> <p>5 fall", is that the work that you did in the Mullins</p> <p>6 case?</p> <p>7 A. It is.</p> <p>8 Q. And what was your intent when you submitted</p> <p>9 Exhibit No. 20?</p> <p>10 A. To get published in a peer-reviewed</p> <p>11 conference proceeding.</p> <p>12 Q. Did you change any of the procedures, the</p> <p>13 data, the findings in Exhibit No. 20, as reported in</p> <p>14 your report from the Mullins case, before submitting it</p> <p>15 for publication?</p> <p>16 MR. THORNBURGH: Objection.</p> <p>17 A. I did not.</p> <p>18 Q. Okay. And to what journal was it submitted?</p> <p>19 A. This is -- this was submitted to the medical</p> <p>20 division, medical device division of the Society of</p> <p>21 Plastics Engineers.</p> <p>22 Q. And has it been accepted for publication?</p> <p>23 A. It has.</p> <p>24 Q. Was it accepted without change?</p>	<p>1 about this?</p> <p>2 MR. THOMAS: Yes.</p> <p>3</p> <p>4 EXAMINATION</p> <p>5 BY MR. THORNBURGH:</p> <p>6</p> <p>7 Q. Doctor, regarding the publication, you said</p> <p>8 it was accepted by the medical device division</p> <p>9 of the --</p> <p>10 A. Society of Plastics Engineers. SPE, it's</p> <p>11 informally known as.</p> <p>12 Q. Are they peer-reviewed?</p> <p>13 A. They are.</p> <p>14 Q. Okay. And did you attempt to submit this</p> <p>15 publication to any other journal?</p> <p>16 A. Not at this time.</p> <p>17 Q. And on the last page of this abstract, you</p> <p>18 note the conflict of interest.</p> <p>19 A. On the last page of the publication, yes, I</p> <p>20 note a conflict of interest disclosure.</p> <p>21 Q. And did you disclose that you were being paid</p> <p>22 as an expert to defend Ethicon in claims that its mesh</p> <p>23 material oxidized and degraded, causing injury to</p> <p>24 patients?</p>
<p>Page 131</p> <p>1 A. Without change.</p> <p>2 Q. And when will it be published?</p> <p>3 A. It will be published at the end of May.</p> <p>4 Q. And will it be presented?</p> <p>5 A. It will be -- also be presented at the end of</p> <p>6 May.</p> <p>7 Q. And where will it be presented?</p> <p>8 A. In Indianapolis.</p> <p>9 Q. At what proceeding?</p> <p>10 A. At the an.tech. conference. It's the annual</p> <p>11 technical conference for the Society of Plastics</p> <p>12 Engineers.</p> <p>13 Q. And what is an.tech. conference to plastics</p> <p>14 engineers?</p> <p>15 A. It's where industrial polymer scientists and</p> <p>16 researchers come together for three or four days to</p> <p>17 author publications and have seminars and technical</p> <p>18 symposium, things like that.</p> <p>19 Q. And who will present that paper?</p> <p>20 A. It hasn't been decided, but it will be either</p> <p>21 Dr. Benight or myself.</p> <p>22 MR. THOMAS: That's all the questions I have.</p> <p>23 Thank you.</p> <p>24 MR. THORNBURGH: Can I ask two questions</p>	<p>Page 133</p> <p>1 MR. THOMAS: Object to the form of the</p> <p>2 question.</p> <p>3 A. I disclosed what's written here in those two</p> <p>4 or three sentences under the disclosure.</p> <p>5 MR. THOMAS: Okay. That's all. I've got to</p> <p>6 go.</p> <p>7</p> <p>8 (Deposition concluded at 11:54 p.m.)</p> <p>9</p> <p>10 * * * * *</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>

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1 STATE OF NEW YORK)
2) SUPREME COURT
3 COUNTY OF NEW YORK)
4 I, Janis L. Ferguson, RPR, CRR, a Notary Public in
5 and for the State of New York, do hereby certify:
6

7 That the witness whose testimony appears herein
8 before was, before the commencement of his/her
9 testimony, duly sworn to testify the truth, the whole
10 truth, and nothing but the truth; that the testimony
11 was taken pursuant to notice at the time and place
12 herein set forth; that said testimony was taken down in
13 shorthand by me and after, under my supervision,
14 transcribed into the English language, and I hereby
15 certify the foregoing testimony is a full, true, and
16 correct transcription of the shorthand notes so taken.

17 I further certify that I am neither counsel for,
nor related to any parties to said action, nor in any
way interested in the outcome thereof.

18 IN WITNESS WHEREOF, I have hereunto subscribed my
name this 20th day of April, 2016.

19

20

21 Janis L. Ferguson, RPR, CRR
Notary Public in and for the State of New York

22
23 My Commission expires: 5/28/2017
24 Registration No. 01FE6282686